UNIVERSITY OF LINCOLN

The development and evaluation of a brief Self-Practice Compassion-Focused Therapy (CFT) intervention as a precursor to treatment as usual (TAU) for trauma patients: A Pilot Randomised Controlled Trial (RCT).

Short Title: Evaluation of a brief CFT intervention for Trauma: A pilot RCT.

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A thesis submitted in part fulfilment of the requirements of the University of Lincoln for the degree of Doctor of Clinical Psychology

2016

Abstract

Background Many people will experience a traumatic event in their lifetime although, only a proportion of people subsequently develop Post-Traumatic Stress Disorder (PTSD). Some individuals will go on to experience distress, but not at a diagnostic level. Treatment has traditionally focused on clinical PTSD, although recent research is considering a dimensional view of trauma by exploring difficulties associated with 'subclinical' PTSD. Various risk factors have been identified in the trauma literature, including trauma type and gender. However more recently research is exploring evolutionary perspectives of trauma and associated factors which may moderate or mediate symptom maintenance. These include self-compassion which is increasingly being considered protective for traumatic stress. Self-practice exercises aimed at developing self-compassion are increasingly being researched although not specifically with trauma survivors.

Aim. This study aimed to implement a feasibility and accessibility study to inform a pilot-RCT of a brief self-practice Compassion Focused Therapy (CFT) intervention for a group of adults accessing specialist services for traumatic stress symptoms.

Method. The study was completed in two phases. Phase one implemented a feasibility test of a five-minute self-practice CFT intervention with a group of eight adults who were accessing community mental health or forensic services. The CFT intervention was amended based on outcomes and phase two implemented a pilot-RCT of the updated intervention (with an immediate and a delayed intervention group) with 10 adults accessing specialist trauma services. Analyses of variance were conducted to evaluate the impact of the intervention on the outcome measures.

Results. Phase one of the study demonstrated large significant effects on the Depression, Anxiety and Stress Scale (DASS-21) following a two-week period of participants practising the CFT intervention. Phase two did not demonstrate significant interaction effects between groups, although there were some significant improvements across time for some measures.

Discussion. The findings from phase one are promising and indicated further research into the use of self-practice CFT exercises as an adjunct to psychotherapies. Recruitment continues in order to add to the findings from phase two of the study.

Acknowledgements

There are many people I would like to thank for their support of my thesis and for making the project possible:

Dr Thomas Schroder and Dr Rachel-Sabin Farrell, for their advice and support in the planning of the project, with the stumbling blocks along the way and for their continued faith that this would be finished on time!

Stephen Regel, for his support with recruitment and continued enthusiasm with the project.

Professor Paul Gilbert, for his advice and permission to use the CFT intervention in the first place.

To Dr Dave Dawson and Dr Nima Moghaddam for their helpful advice around statistics and to Dr Caroline Falconer, whose interest in HRV helped me finally find a simpler explanation!

The clients who committed their time to engaging in the study and provided such enthusiastic feedback about the intervention and their experiences.

And of course, my fiancé for fuelling me with copious amounts of coffee, and my family and friends for their patience.

Statement of Contribution

As the primary researcher I was responsible for the research design, the ethical applications, writing the literature review, collecting, scoring and analysis of data and preparing the written thesis and journal paper.

Dr. Thomas Schroder (Primary Research Supervisor) contributed to the research design, offered support with ethical issues, gave time to overseeing analysis of data and proof read a draft of the journal paper.

Dr Rachel Sabin-Farrell (Research Supervisor) also contributed to the research design, supported with ethical processes and recruitment issues, and proof read a draft of the journal paper.

Stephen Regel (Local Collaborator) oversaw the implementation of the study and assisted with recruitment by offering information to his clients about the project.

Professor Paul Gilbert provided a compassion focused intervention script which he kindly permitted me to adapt and use for the thesis project.

Contents

Tables and Figures

List of Appendices

Systematic Review

Can self-help interventions for trauma reduce Posttraumatic Stress Disorder symptoms? A meta-analysis.

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Abstract

A systematic literature review of self-help interventions for posttraumatic stress disorder was carried out to investigate their effectiveness. Previous reviews have been conducted with other clinical populations or with specific focus mode of intervention delivery. The current review considers self-help for trauma, without therapeutic contact. Searching of PILOTS, EMBASE, PsycINFO, Medline and the Cochrane Library resulted in 10 studies being included in the review which describe the effects of self-help on posttraumatic stress symptoms. A meta-analysis was conducted on seven of the included studies and found a small significant overall effect of self-help for trauma compared to waiting list or active controls. This review suggests the need for more research into the effects of self-help for trauma remains. Of benefit would be additional research to compare the content of self-help intervention, level of symptom severity amenable to such interventions, and the potential for self-help interventions as adjuncts to trauma-focused psychotherapy.

Key Words: posttraumatic stress disorder; PTSD; self-help interventions.

Introduction

Traumatic events are not uncommon and although not all individuals develop psychological difficulties as a result (Bonnano, 2008) a significant number of people experience symptoms of posttraumatic stress disorder (PTSD) (Keane, Marx, Sloan & DePrince, 2010). PTSD, characterised by symptoms of intrusive thoughts, avoidance behaviours and negative alterations in cognitions and mood, is a 'trauma-and-stressor-related disorder (Diagnostic and Statistical Manual of Mental Disorders [DSM-5]; American Psychiatric Association, 2013). Prevalence rates for PTSD for European countries are estimated at 0.56% - 6.67% equating to approximately 7.7 million people (Wittchen et al., 2011).

Current National Institute of Health and Clinical Excellence (NICE, 2005) guidance recommends that cognitive behaviour therapy (CBT) focusing on avoidance behaviours and exposure to trauma memories, or eye movement de-sensitisation and reprocessing (EMDR; Shapiro, 1989) should be offered. However, many individuals do not seek treatment (Gavrilovic, Schützwohl, Fazel & Priebe, 2005). Reasons include limited access and cost (Pietrzak, Johnson, Goldstein, Malley & Southwick, 2009). Exploring the effects of self-help interventions for trauma may provide more scope for individuals to access treatment. NICE guidelines recommend that research needs to include randomised control trials (RCTs) using guided self-help interventions to evaluate the effects on mild-moderate PTSD symptoms. Lewis and colleagues have begun this process in the development of a guided self-help programme and an RCT looks promising in the near future (Lewis, Roberts, Vick & Bisson, 2013).

Several systematic reviews of self-help interventions exist for anxiety disorders and other common psychological difficulties (e.g. Lewis, Pearce & Bisson, 2012; den Boer, Wiersma & Van Den Bosch, 2004; Hirai & Clum, 2006). These evaluate a variety of self-help interventions including manualised or internet-based therapy and writing exercises. Recent studies have explored these mode of interventions specifically for PTSD (Ivarsson et al., 2014; Sloan, Gallagher, Feinstein, Lee & Pruneau, 2011; Benight, Ruzek & Waldrep, 2008) and some reviews of their effects are available (Amstadter Bromun-Fulks, Zinzow, Ruggiero & Cercone, 2009; van Emmerik, Reijintjes & Kamphuis, 2013). However there is little research combining intervention types to consider the efficacy of self-help for PTSD.

Newman, Szkodny, Llera and Przeworksi, (2011) offer definitions of self-help: self-administered (SA; therapist contact only for assessment), predominantly self-administered (PSA; therapist contact for instructions and guidance not exceeding 90 minutes), minimal contact (MC; more than 90 minutes of therapeutic assistance) and therapist administered (TA; regular contact with a therapist). For the purposes of this review SA and PSA are included. Previous reviews have compared the different levels of assistance in interventions and found that effect sizes were comparable (Cuijpers, Donker, van Straten, Li, & Andersson, 2010; Gould & Clum, 1993). If SA and PSA are found to be effective, this is likely to have wider implications on costs and accessibility; this is less well understood than the TA literature. Whilst some reviews find face-to-face more effective, self-help is more effective than waiting lists (Lewis, et al., 2012). Non-guidance contact (i.e. SA) was found in meta-analyses to support significant clinical progress similar to therapist input for social phobia and comparable progress to Treatment As Usual (TAU) for depression (Talbot, 2012). This systematic review considers the effects of SA/PSA interventions as a potential means for treating PTSD symptoms given the lack of evaluation in the literature for this clinical population. This may offer implications for therapy waiting lists and therapist costs, identifying potential for more accessible means of intervention.

Method

To answer the question as to whether self-help interventions for PTSD can reduce symptomatology, inclusion criteria were completed using a PICO template (Richardson, Wilson, Nishikawa, & Hayward, 1995):

- *Population*: Individuals with PTSD symptoms (diagnosis of PTSD or reporting of symptoms).
- *Intervention*: SA and PSA targeting PTSD symptoms.
- *Comparison:* Waiting list or active control (non-trauma related intervention).
- *Outcome:* Decrease in PTSD symptoms, measured by a self-report PTSD scale.

The review question was considered in the context of the prevalence of PTSD and the lack of focused literature on SA/PSA interventions for these individuals. It was decided that quantitative reports of case series would be included to provide additional information of the effects of self-help interventions on PTSD.

Selection

Following development of the PICO and initial scoping searches the inclusion criteria were finalised. Inclusion criteria required: (a) quantitative research, (b) participants over the age of 18 years who had experienced at least one trauma, (c) original and published data (d) peer-reviewed articles (e) written in English, (f) a self-report measure of PTSD symptoms, (g) an intervention which could be defined as SA or PSA.

In addition specific exclusion criteria were applied: (a) additional training sessions from therapists prior to self-help interventions, (b) interventions targeting co-morbid clinical problems (e.g. substance misuse) and (c) the addition of group sessions. These factors were considered to be potential confounding variables. Training and group sessions may act as a form of clinical guidance or contact; interventions targeting co-morbidity do not allow accurate distinction between aspects of the intervention specifically targeted at PTSD symptoms.

Searching

Several search strategies were used to identify relevant papers in major databases: PILOTS, EMBASE, PsycINFO and the Cochrane Library. Articles considered were not restricted by year due to the limited amount of research on self-help interventions specifically for PTSD and included journals up to March 2015. Within each database, the following search terms were used: posttraumatic stress, post-traumatic stress, trauma, PTSD, self-help, self-instruct*[3], self-directed, individualized instruction, survivors, and self-administ*. Relevant MeSH headings were used where appropriate, as well as Boolean phrases and mapped subjects. Clinicaltrials.gov was searched for any additional articles. Hand searching of all full text articles was also conducted.

Data abstraction

Data extraction forms from the Joanna Briggs Institute (JBI; 2011) were used to identify relevant information from each experimental and case series study, including sample size, population, intervention type and outcome data. The Critical Appraisal Skills Programme (CASP, 2014) checklist was considered; however, it was felt the adaptation of the JBI checklist was more appropriate given the range of studies initially included and the

[3] denotes where a wildcard symbol was used to expand the search term.

focus of the current review. A summary of study characteristics can be found in Table 1. Effect sizes were calculated where possible for the purpose of additional meta-analysis.

The JBI critical appraisal checklists were used for both experimental and case series studies. These consider various implications of bias when reporting results of studies (JBI, 2011) and therefore identify valuable information for synthesis of the data. They were adapted to include an additional item about the clarity of the intervention description. This captured data on theoretical models underpinning the intervention and details of its content.

Data synthesis

Standardised effect sizes for all studies were calculated using Pearson's correlation coefficient *r*. For experimental studies, effect sizes of pre- to post-intervention scores and pre- to follow-up scores were calculated in order to investigate the maintenance of any effects following intervention. These were calculated between-groups.

For the case series/single cohort studies, the within-group effect sizes were calculated in order to evaluate the effects over time. These are summarised narratively and are not included in the meta-analysis.

Meta-analysis

Data were inputted into the Cochrane Collaboration's Review Manager 5.3 software for Windows (RevMan; The Cochrane Collaboration, Copenhagen, 2014) to analyse continuous data (PTSD symptom change). Standardised mean differences (SMDs) were used to account for variability in outcomes measures used and 95% confidence intervals (CIs) were calculated for between-groups effects. Analyses were again conducted on pre- to post-intervention scores, and pre- to follow-up scores as with the individual studies. Where studies provided effects sizes for subscales of measures, the mean effect size of all PTSD measure subscales was calculated, ensuring a single effect size for each sample. For studies which included three-arm designs, the control data was taken from the arm consisting of no treatment, again providing one effect size enabling comparisons of SA/PSA to no treatment or non-therapeutic treatments.

As considerable heterogeneity was expected given the nature of social sciences research (Field & Gillett, 2011) effect size calculations employed a random-effects method allowing for a more conservative approach to reporting effect sizes by using the inverse-

variance approach (DerSimonian, 1986). The I^2 statistic was calculated in order to test for heterogeneity which is provided as a percentage (25% = low; 50% = moderate; 75% = high: Higgins and Green, 2011). Sensitivity analyses were conducted to consider whether restriction to RCTs (i.e. studies with stronger experimental control) affected outcome of meta-analysis. RevMan provides effect sizes as Hedges adjusted *g*, therefore conversions to effect size *r* were calculated to provide comparable information to individual study effects. Effect sizes of r=0.10 are small, with r=0.30 and r=0.50 representing medium and large effect sizes respectively (Cohen, 1992).

Results

Electronic searching identified 922 articles which were reduced to 491 after removing duplicates (Figure 1.). Titles and abstracts were reviewed for relevance to the review question resulting in 29 potential papers for which the full texts were obtained. Another six articles were obtained through hand-searching bibliographies. A further 25 papers did not meet the inclusion criteria, leaving 10 studies to be included in the systematic review. One study included data on two parallel samples (10) which were independent of one another, therefore providing two sets of data. These have been considered separately (Table 1).

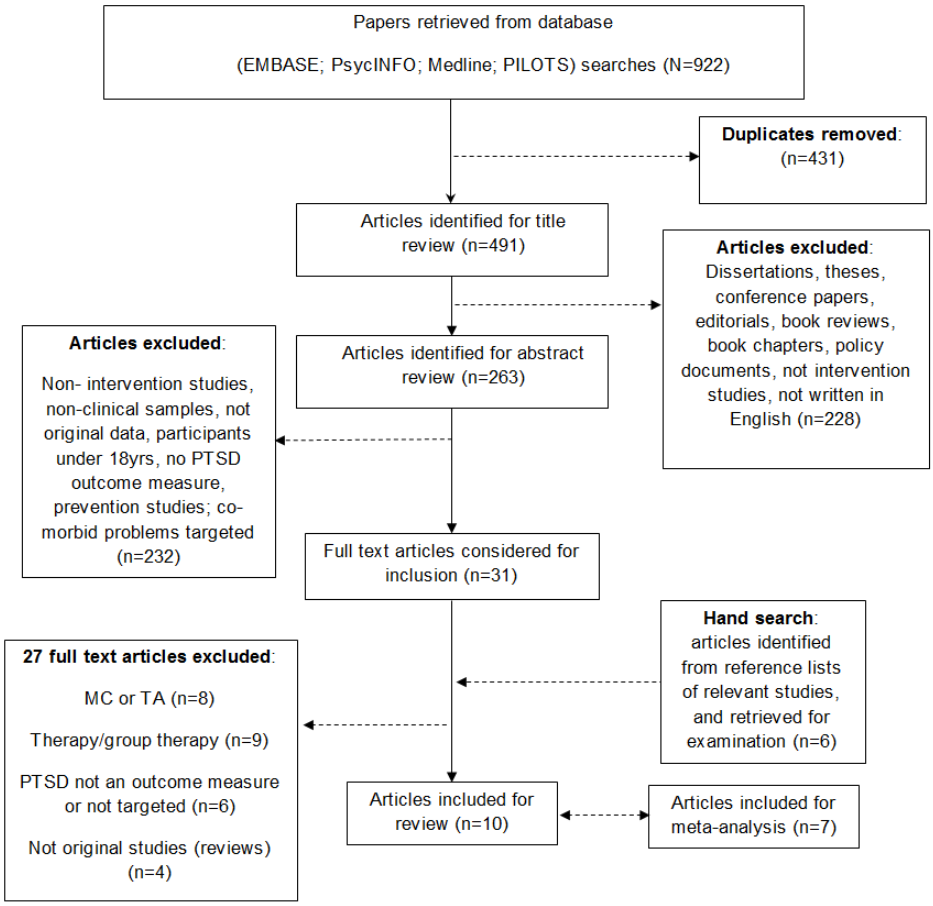

Figure 1. Flowchart of study inclusion.

Characteristics of included studies

The 10 studies included a total of 491 participants over 11 distinct samples. 60 of these were in case series papers. The population samples varied in their trauma experience which included natural disasters (n=3), combat trauma (n=3; includes student veterans), road traffic accidents (n=2) and a combination (n=2). The severity of self-reported PTSD symptoms ranged from minimal to severe with a majority of the overall sample being female. A range of PTSD symptom assessments were used, with the most common being variations of the PTSD Checklist (PCL; Weathers & Ford, 1996) and the Posttraumatic Diagnostic Scale (PDS; Foa, Cashman, Jaycox & Perry, 1997).

Theoretical models used in the self-help interventions included CBT (n=5) with two of these studies combining CBT with Acceptance and Commitment Therapy (ACT) principles. The remaining five studies did not specify a theoretical model. There were a range of SA/PSA intervention types including; internet programmes (n=4), writing interventions

(n=3), self-help manuals (n=2), and a combination (CD, DVD and manual; n=1). There were an equal number of studies which utilised PSA and SA interventions. Treatment length ranged from three sessions (2, 7, 9) to 12 sessions (5).

For the two case series/single cohort studies which provided relevant data, within-group effect sizes were calculated for post and follow-up. The seven experimental studies were able to be reviewed as part of the meta-analysis. This has been presented as eight samples due to the distinct parallel samples in one study being analysed separately in the paper (10). Five of these eight provided adequate follow-up data to be reviewed in the meta-analysis.

Data synthesis

The three case series studies used different methods for intervention (manualised, writing and multi-media). Despite the differences in methods, the two studies that provided data to report effect sizes demonstrated medium to large effects over time for the self-help interventions ([1] r = 0.69 and [3] r = 0.39; Table 1). These interventions were SA, demonstrating some efficacy for interventions only utilising contact with therapists for assessment purposes. However, outcomes of within-subject data are difficult to generalise across populations and are viewed as overestimations of the actual effects (Maxwell & Delaney, 2004).

Briefly, the effect sizes for the remaining experimental studies are varied; four demonstrated no effect (2, 5, 7, 8), one demonstrated a small effect (10) and two demonstrated medium effects (6, 9). However, these should be interpreted with caution when evaluating an overall effect of self-help interventions for PTSD due to the differences in sample sizes and study quality. As a result, the meta-analysis offers a more accurate evaluation of effect sizes by utilising methods of weighting the studies (Higgins & Green, 2011).

Table 1. Summary of studies included.

Study	Authors	Study Method	Participants	Level of contact	Intervention	Control Group	Outcome Measure	*ES* post (*r*)	*ES* Follow-up (*r*)
1	Başoğlu, Salcioğlu & Livanou (2009) (w/g *ES*)	CS	Earthquake survivors (n=8)	SA	SH manual (information, self-monitoring, self-exposure, coping skills)	NC	TSSC	0.69	1month: 0.65 3month: 0.65 6month: 0.71
2	Bugg, Turpin, Mason & Scholes (2009)	RCT	RTA survivors, assault victims and occupational accidents from A&E (n=67)	SA	Writing intervention (focused on thoughts and feeling about RTA) & SH booklet (info and advice)	SH booklet only	PDS	0.07	0.17
3	Bush et al.(2014) (w/g *ES*)	CS	Student veterans (n=11)	SA	PTS workshops (8 online sessions; stress inoculation techniques, CBT and ACT elements)	NC	PCL-M	0.39	NFU

Study	Authors	Study Method	Participants	Level of contact	Intervention	Control Group	Outcome Measure	*ES* post (*r*)	*ES* Follow-up (*r*)
4	Collinge, Kahn & Soltysik (2012)	CS	Combat veterans (n=41)	SA	CD (mind/body practices), DVD (massage techniques for stress reduction), manual (instructions for the above)	NC	PCL-C	N/A	N/A
5	Ehlers et al. (2003)	RCT	RTA survivors from A&E (n=80)	PSA	SH Booklet (40 min instruction session + 64 pages following CBT for PTSD)	Repeated assessments or CT (12 sessions of CBT for PTSD)	PDS	SH < CT: 0.55 SH >RA: 0.13	SH<CT: 0.6 SH<RA 0.03
6	Hirai & Clum (2005)	ES	Community population (RTAs, interpersonal violence, witness of events, losses and disease) (n=27)	PSA	8-week Internet CBT program (info, relaxation, cognitive techniques, exposure)	WL	IES-R	0.37	NFU

Study	Authors	Study Method	Participants	Level of contact	Intervention	Control Group	Outcome Measure	*ES* post (*r*)	*ES* Follow-up (*r*)
7	Possemato, Ouimette & Knowlton (2011)	RCT	Veterans Affairs (VA) service users (n=26)	PSA	Internet writing exercises (focused on traumatic event)	Non-trauma writing exercises	PCL-M	0.017	NFU
8	Steinmetz, Benight, Bishop & James (2012)	RCT	Hurricane Ike survivors (n=56)	PSA	6 week online intervention (interactive; videos, tests) focused on memories/triggers, self-talk and coping	UC or Information	MPSS	SH < UC: 0.07 SH > IG: 0.15	NFU
9	Stockton, Joseph & Hunt (2014)	ES	Research Volunteers with experiences of trauma-related distress (n=24)	PSA	Writing intervention (3 x 15min sessions focus on emotions around traumatic event)	Non-trauma writing exercises	IES-R	0.34	0.27
10a	Wang, Wang & Maercker (2013)	RCT	Rural sample: earthquake survivors (n=90)	SA	6 week online intervention (videos, tests) focused on memories/triggers, self-talk and coping	WL	PDS	0.26 Within 0.44	0.14

Study	Authors	Study Method	Participants	Level of contact	Intervention	Control Group	Outcome Measure	*ES* post (*r*)	*ES* Follow-up (*r*)
10b	Wang, Wang & Maercker (2013)	RCT	Urban samples: trauma survivors (n=61)	SA	6 week online intervention (videos, tests) focused on memories/triggers, self-talk and coping	WL	PDS	0.21 Within: 0.40	0.05

Note. CS, case series study; PS, pilot study; RCT, randomised controlled trial; ES, experimental study; RTA, road traffic accident; A&E, accident and emergency, SA, self-administered; PSA, predominantly self-administered; SH, self-help; PTS; posttraumatic workshops; CBT, cognitive-behavioural therapy; ACT, acceptance and commitment therapy; CD, compact disc; DVD, digital versatile disc; PTSD, posttraumatic stress disorder; NC, no control group; CT, cognitive therapy; WL, waiting list; UC, usual care; TSSC, traumatic stress symptom checklist; PDS, post-traumatic diagnostic scale; PCL-M, posttraumatic checklist – military; PCL-C, posttraumatic checklist – civilian; IES-R, impact of events scale – revised; MPSS, modified PTSD symptom scale; RA, repeated assessments; IG, information group; NFU, no follow up; N/A, not applicable.

Table 2. Meta-analyses of the effects of SA/PSA interventions for adult PTSD.

	Samples (N = 8*)*	***Hedges g* (SMDs)**	**95% CI**	I^2	***r***
Effect sizes at post-test					
All comparisons	8	0.26	-0.05, 0.56	51	0.13
RCTs only	5	0.35	0.05, 0.64	39	0.17
	(N=5)				
Effect sizes at follow-up					
All comparisons	5	0.10	-0.36, 0.16	3	0.05
RCTs only	4	0.17	-0.43, 0.10	0	0.09

Note. Where 95% CIs for SMDs include 0, the overall treatment effect failed to reach statistical significance at p < .05.

Meta-Analysis

Of the 431 participants in the experimental designs, 384 were included in the meta-analysis. 187 were in the SA/PSA condition and 197 in the control/waiting list condition. These figures exclude 28 participants from the cognitive therapy arm in one paper (5) and 19 participants from the information condition in another (8) in order to provide one effect per study for analysis. Eight distinct samples were analysed for the effects of SA/PSA interventions specifically on PTSD symptoms. Table 2 summarises the treatment effects on outcomes.

The overall effect size for all self-help studies compared to waiting list or non-therapeutic interventions at post-test was SMD = 0.26 (95% CI -0.05 to 0.56, z = 1.66, p =0.10, 8 samples: n=384). Heterogeneity was moderate and significant. (I^2 = 51%, p = 0.05). Converted effect size *r* = 0.13 demonstrated the small overall effect size on treatment outcomes.

When restricting analyses to RCT studies only, heterogeneity reduced and was no longer significant (I^2 = 39%, p = 0.16). This analyses resulted in a greater overall effect size that was statistically significant (SMD = 0.35, 95% CI 0.05 to 0.64, z = 2.29, p = 0.02, 5 samples; n=307). Converted effect size *r* = 0.17 remained small although significant. Sub-

group analyses were considered. However, there were limits to such analyses given the small number of studies and overall sample sizes. In addition, other influences between the studies could not be controlled for and therefore the relevance of the data is likely to be limited.

Analysis of the follow up data (Table 2) confirms the small effect sizes found in post-measures, which do not reach significance (SMD = 0.10, CI -0.36 to 0.16, z = 0.76, p =0.45, 5 samples, n=248).

Quality of included studies

Using the JBI checklist, a scoring criterion was implemented. The main items are presented in Tables 3 and 4. All studies were given a score out of eight. Ratings of 0-2 were considered 'poor' quality, 3-5 as 'fair' and 6-8 as 'good' quality. Quality of the studies varied between designs, although all of the experimental studies were rated fair to good. Within experimental studies, four of the seven studies (2, 5, 6, 7) did not account for attrition bias by including non-completer data in an intention-to-treat analysis and none of the papers provided clear information as to whether outcomes assessments were blinded (therefore this was not included in the table). All experimental studies used randomised allocation to intervention and blinded participants, with the exception of one (8). This was due to the authors restricting randomisation so as to provide comparable groups. All experimental studies demonstrated identical conditions other than the interventions and had comparable groups at baseline with the exception of gender (2). It was considered to exclude studies based on the evaluations however due to the few studies included from the outset it was deemed to be beneficial to retain all experimental studies to allow for a larger overall sample.

In relation to the case series, the quality was reasonably comparable, with one study of poorer quality than all other studies (3). Efforts were made to account for confounding factors in the two studies which identified them (1, 3) via study methods or exclusion criteria. Of all 10 studies, four studies administered pre and post measures only, and for the remaining six studies the follow-up periods ranged from one to nine months.

Table 3. Summary of the critical appraisal of experimental studies.

	Study	Study Method	Random assignment to treatment	Blind	Withdrawal data analysed	Comparable groups	Identical conditions	Follow-up period	Clear intervention	Total score
2	Bugg, Turpin, Mason & Scholes (2009)	RCT	1	2	0	1	1	1	0	6
5	Ehlers et al. (2003)	RCT	1	2	0	1	1	1	1	7
6	Hirai & Clum (2005)	ES	1	1	0	1	1	0	1	5
7	Possemato, Ouimette & Knowlton (2011)	PS	1	1	0	1	1	1	0	5
8	Steinmetz, Benight, Bishop & James (2012)	RCT	0	0	1	1	1	0	1	4
9	Stockton, Joseph & Hunt (2014)	ES	1	?	?	1	1	1	0	4
10	Wang, Wang & Maercker (2013)	RCT (parallel samples)	1	2	1	1	1	1	1	8

Note. 0, 'no'; 1, 'yes'; Blind (0, no blinding, 1, participants OR researchers blinded; 2, participants AND researchers blinded.

Table 4. Summary of the critical appraisal of case series papers.

	Study	Study Method	Random sample	Clear inclusion criteria	Confounding factors raised	Confounding factors addressed	Withdrawal data analysed	Follow-up period	Clear intervention	Clear outcome measures	Total quality score
1	Başoğlu, Salcioğlu & Livanou (2009)	CS	0	1	1	1	0	1	1	1	6
3	Bush et al.(2014)	CS	0	1	0	0	0	0	1	1	3
4	**Collinge, Kahn & Soltysik (2012)**	**PS**	**0**	**0**	**1**	**1**	**0**	**0**	**1**	**1**	**4**

Note. 0, 'no'; 1, 'yes'.

Discussion

Main findings

The current review aimed to consider the available evidence for a range of SA and PSA interventions targeted at reducing PTSD symptoms. Analyses of specific interventions for PTSD such as internet programmes or writing exercises (van Emmerik et al., 2013; Sloan et al., 2011) previously demonstrated large effects on PTSD symptoms compared to waiting lists. Results of the meta-analyses demonstrated that SA/PSA interventions resulted in small effects which did reach statistical significance when restricting quality criteria to RCT studies, offering some support for the current self-help efficacy literature in other clinical populations (Lewis, et al., 2012; den Boer et al, 2004; Hirai & Clum, 2006).

The studies excluded from the meta-analysis demonstrated small to medium effects on treatment outcomes, although this within-group data may represent an overestimation of effects (Maxwell & Delaney, 2004). Effect sizes for individual studies ranged from r=0.07 (2) to r=0.69 (1) demonstrating a wide range. This may be a reflection of the range of intervention types, sample sizes and study designs. The results from the meta-analysis offer a more accurate estimate of effects and suggest the effects of self-help are somewhat smaller.

Implications

The findings of this review suggest that SA and PSA interventions may demonstrate small effects on reducing PTSD symptoms when under RCT conditions. This provides support for the NICE recommendations for further investigation of the efficacy of 'guided' self-help (NICE, 2005). It may be that *guided* self-help is more effective for individuals experiencing PTSD than SA/PSA self-help. This has previously been considered in relation to other psychopathology and has found that guided self-help is comparable to face-to-face psychotherapy (Cuijpers et al., 2010). Further investigation is being pursued by other authors and may provide more information about the optimum level of therapist input (Lewis et al., 2013).

Given the potential for financial savings of self-help interventions (Lewis et al., 2012) and the effects on other symptomatology, more studies should rigorously explore the effectiveness across intervention modes and severity of PTSD symptoms. It may be

that SA/PSA interventions are more effective when individuals have mild to moderate PTSD than more severe symptoms, as chronic symptoms may require more intensive therapy (Bugg et al., 2009).

The literature around anxiety and depression is more optimistic and it may be that SA/PSA interventions specifically targeting PTSD are unsuitable. Difficulties with emotions associated with their experiences, such as guilt and shame (Harman & Lee, 2010) may impede trauma-focused SA. Treatment focused on these difficulties may be more beneficial initially. As such there is potential for research to consider the effect of SA/PSA interventions as adjuncts to face-to-face psychotherapy. This would enable effective self-help interventions to be offered (focused on emotional difficulties) to trauma clients whilst on waiting lists for trauma-focused therapies. It has not yet been evaluated as to whether this would impact on outcomes of formal therapy. The current meta-analysis concluded significant yet small effect sizes on direct reductions in PTSD symptoms and therefore it may warrant investigation of the effects of self-help during waiting list periods on face-to-face psychotherapy outcomes.

The variety of intervention types in the current review is likely to have influenced the effect size estimates. Some interventions included self-directed exposure techniques which participants may find difficult due to the potential for experiencing them as threatening (Ehlers & Clarke, 2008), particularly as the SA/PSA intervention methods excluded any element of training in therapeutic techniques. However, research indicates that many survivors of trauma find exposure techniques useful even in the absence of therapists (Başoğlu, Salcioğlu & Livanou, 2007). Further investigation of the components of self-help interventions would identify those which are beneficial for SA/PSA and those which may be more suited to formal psychotherapy. There were several limitations to the included studies and the review itself

Review Limitations

The overall sample size was small, possibly due to the decision to include only peer reviewed articles. Whilst this enabled a more sound evaluation through meta-analysis, it may have been beneficial to source grey literature to add to the overall numbers included in the study. Future reviews may benefit from this wider scope.

Literature Limitations

The variation in interventions meant that explanation of the small effect sizes is difficult to attribute to any one mode or theoretical model. In addition, only half of the included studies reported clear definitions as to the theory or techniques used. Should more studies evaluate different modes of self-help intervention, the availability of pooled data would allow for more coherent comparisons of intervention types.

The populations within samples experienced comparable traumas (e.g. natural disasters [1, 8, 10], combat exposure [3, 4, 7]). However the between-groups effect estimates pooled this variety of traumas. Therefore it cannot be confidently generalised that effects of one intervention on a specific trauma group apply to all trauma groups. Future research would benefit from incorporating populations with varying traumatic experiences to test whether the efficacy of SA/PSA interventions on PTSD is independent of the trauma event/characteristics.

Several of the studies highlight problems with participants adhering to the treatment instructions (8, 9, 10). The benefits of prompting and therapist contact to encourage adherence in self-help interventions remain unclear (Cuijpers & Schuurmans, 2007) and further understanding is needed. However, individuals may have difficulty fully adhering to strict intervention protocols due to lifestyles and therefore access what they can fit in (Litz, Williams, Wang, Bryant & Engel, 2004).

Conclusion

Financial costs and access to treatment encourage research into alternative treatment methods in order to allow greater access for individuals in need of psychological intervention. This review and meta-analysis found limited evidence for SA and PSH treatments reducing PTSD symptoms. However, the overall sample was small, with large variability in traumatic experiences, symptom severity and intervention methods, making it difficult generalise results from the individual studies. Further research is required in evaluating the types of intervention techniques used, the potential for self-help to act as an adjunct to trauma-focused therapies to improve outcomes, and to find optimum levels of therapist input.

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Journal paper

The development and Evaluation of a Brief Self-Practice Compassion-Focused Therapy (CFT) Intervention as a Precursor to Treatment as Usual (TAU) for Trauma Patients: A Pilot Randomised Controlled Trial (RCT)

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Abstract

This study formed the second phase of a larger research project; a pilot-Randomised Control Trial (RCT) with participants experiencing traumatic stress symptoms Participants were required to be on a waiting list for therapy at a specialist trauma service. A three-week self-practice CFT intervention was evaluated in relation to factors suggested to be associated with trauma symptom maintenance. 10 participants were randomised to either immediate CFT intervention (n=5) or a delayed intervention waiting-list control group (n=5). Measures were administered pre-, mid- and post-intervention. Whilst no significant interaction effects were found between time and group, main effects of time were found for depression, and for trauma symptoms of intrusion, avoidance and hyperarousal. Main effects of group were found for avoidance, with the immediate CFT group demonstrating lower scores throughout the study. Main effects of time were also found for significant decreases in negative scales of self-criticism. A measure of Heart Rate Variability was explored, although demonstrated non-significant changes. The absence of significant interaction effects suggests the conclusion that the CFT intervention did not significantly improve trauma symptoms for this clinical sample. Implications for future research include evaluating the intervention on a larger scale with an active control group with which to compare.

Trial registration number 160094; clinicaltrials.gov.

Key Words: posttraumatic stress disorder; PTSD; trauma; traumatic stress; self-help; self-practice; compassion; self-compassion; interventions; pilot RCT.

Introduction

Many people will experience a traumatic event in their lifetime although not all will develop Post-Traumatic Stress Disorder (PTSD) (Bonanno, 2008). A traumatic event is defined as exposure to death, threatened death, or actual or threatened serious injury or sexual violence (DSM-5; American Psychological Association [APA], 2013). However there remains debate over whether this should be objectively defined based on event-related factors, or whether it is a subjective phenomenon related to experiential impact on the individual (Eagle & Kaminer, 2015). Nevertheless, it is a prevalent issue.

The National Co-Morbidity Survey Replication (NCS-R; Kessler, Chiu, Demler, Merikangas, & Walters 2005) found that in Americans, lifetime PTSD prevalence was 6.8%. Prevalence rates based on diagnostic interviews for PTSD in the United States has varied widely between 12.8% and 46% (Franklin, Sheeran, & Zimmerman, 2002; Villano et. al., 2007). However for those who have experienced a traumatic event who do not receive a diagnosis of PTSD, they may still experience traumatic stress symptoms associated with heightened distress and impairments in daily functioning (Cukor, Wyka, Jayasinghe, & Difede,. 2010; Dickstein, Walter, Schumm, & Chard, 2013), with similar prevalence rates for diagnosed PTSD (Schnurr, 2014).

Exposure to trauma may also result in associated symptoms of depression and anxiety (Mayou, Bryant, & Ehlers, 2001; Resick & Schnicke, 1992). Co-morbidity rates for traumatic stress range from 21% to 94% for depression and 39% to 97% for anxiety (Ginzburg, Ein-Dor, & Solomon, 2010; Kessler, et. al., 2005; Pietrzak, et. al., 2011). However, differentiating these diagnoses may be impeded by overlapping symptoms and/or risk factors (Spinhoven, Penninx, van Hemert, de Rooij, & Elzinga, 2014) and such figures do not answer the question of what influences an individual's response to trauma and the trajectory of their distress. It has been suggested that those experiencing traumatic stress symptoms are at risk of developing diagnostic levels of symptomology (Mylle & Maes, 2004).

Traumatic stress is considered to develop into problematic symptoms when initial innate responses to life threatening events are not well-processed (at a conscious or unconscious level) and associated memories may become 'stuck' (Horowitz, 1983).

However, event-related information processing, and appraisals of ongoing threat (Ehlers & Clarke, 2008) do not fully explain why traumatic stress symptoms may be maintained. It is therefore important to consider additional influential factors in the development and maintenance of traumatic distress.

Mediating Factors

Self-criticism. Defined as a combination of 'inadequate' and 'hated' beliefs about the self (Gilbert, Baldwin, Irons, Baccus & Palmer, 2006), self-criticism is suggested to be a pervasive feature of psychopathology (Gilbert & Irons, 2004). These beliefs are influenced by a level of self-loathing and hostility, and difficulty in generating feelings of reassurance and self-soothing (Gilbert, 2000; Whelton & Greenberg, 2005). Self-criticism can trigger anxiety experiences (Whelton & Greenberg, 2005) and can impede the ability to engage with or experience positive emotions (Gilbert et. al., 2006). The resulting sense of threat or shame (Harman & Lee, 2010) may mediate the initial response to traumatic experiences, as well as moderate the maintenance of symptoms. This may be due to high self-critics experiencing difficulties in reassuring themselves in relation to ongoing symptoms. (See Figure 2 for an overview of pathways between factors).

Research suggests that whilst positive emotions can minimise threat-based negative affect (Fredrickson, 2001) self-criticism may act to moderate maintenance of trauma symptoms (i.e. feelings of depression, anxiety and stress). Individuals who have limited ability to experience or nurture positive emotions may be less able to experience a reduced intensity of negative ones and as such may exacerbate symptom maintenance. Indeed, self-criticism has been found to associate with increased psychopathology, including PTSD (Brewin & Holmes, 2003; Murphy et al., 2002; Whelton & Greenberg, 2005; Lee, 2005).

Heart Rate Variability (HRV). An evolutionary perspective offering an understanding of traumatic responses is Polyvagal Theory (Porges, 2007). Porges proposes that humans have a hierarchy of strategies employed by the Autonomic Nervous System (ANS) to regulate physiological arousal when faced with danger. The most sophisticated neural circuit, the 'Social Engagement System' allows us to

subconsciously interpret our environment as safe or threatening. Termed 'neuroception', (Porges, 2011) this is an unconscious neural process using cues in the environment and viscera to evaluate risk. Research indicates that some individuals including those who are traumatised have difficulty with accurate neuroception often leading to appraisals of their environment as dangerous even when it is safe (Porges, 2007).

When the regulation systems are working effectively, a ventral vagal 'brake' is applied to calm our threat response system (Porges, 2011) and inhibits the use of the sympathetic nervous system. The nerve produces a pattern of heart rate fluctuations, known as HRV (Appelhaus & Luecken, 2006), measurement of which provides information about the efficiency of the vagal 'brake' and offers a non-invasive measurement of the social engagement system, (Porges, 2011a).

High HRV, reflecting an adaptive use of the 'vagal brake', is associated with the ability to self-soothe when faced with threat (Rockcliff, Gilbert, McEwan, Lightman & Glover, 2008; Porges, 2007). For individuals experiencing trauma symptoms, lower vagal regulation has been found (Chang et al. 2013; Guédon-Moreau et al. 2012) as well as indications of lower parasympathetic activity and rigid response regulation (Lee & Theus, 2012; Hauschildt, Moritz, Jelinek & Peters, 2011; Tan, Dao, Farmer, Sutherland, & Gevirtz, 2011; van der Kolk, 2006). A low HRV may therefore play a role in mediating traumatic stress symptoms following an event. It has been indicated that individuals with high HRV are better at constructively coping with distress (Fabes & Eisenberg, 1997), perhaps promoted by an increased ability to engage in affiliative behaviours enabling self-regulation (Schwerdtfeger & Schlagert, 2011) and actively seeking social support networks to manage distress, (Geisler, Kubiak, Siewert, & Weber, 2013). Exploring ways to support regulation of these systems and promote access to the social engagement system is important.

Moderating Factors

Self-compassion. This has been found to be a protective factor against psychopathology, including traumatic stress (Gilbert, 2009; Neff, 2003; Kuyken et al. 2010; Thompson & Waltz, 2008). Self-compassion is considered an emotion regulation strategy (Neff, 2003) and associations between high self-compassion and reduced

thought suppression may indicate greater resilience to traumatic stress (Cooper, 2011). In particular, developing self-compassion has demonstrated positive effects on symptoms of depression, anxiety and stress (McEwan & Gilbert, 2016) and is becoming more integrated in therapy (Gilbert, 2010; Lee & James, 2012). However some individuals experience a fear of compassion (Rockliff, Gilbert, McEwan, Lightman & Glover, 2008). An inability to experience self-compassion may impact on therapeutic outcomes, (Gilbert, et al. 2011; Hagenaars & Minnen, 2010). As such, high self-compassion could moderate the maintenance of trauma symptoms and increase positive outcomes in therapy. Indeed this may additionally support a reduction in self-critical hostility (Gilbert, 2009).

Social safeness. Social safeness, an emotional experience arising from the presence of threat-regulating others (Gilbert, 2010), may be an important factor in moderating the likelihood of ongoing traumatic distress and counter some experiences related to self-criticism. Social safeness negatively correlates with depression, anxiety and self-criticism (Gilbert et al. 2008) and predicts trait self-criticism (Kelly, Zuroff, Leybman & Gilbert, 2012). Threat processing is suggested to be regulated through feelings of affiliation and soothing, enhanced by social safeness (Depue & Morrone-Strupinsky, 2005; Kirsch et al., 2005) and therefore may be an important factor to consider in the maintenance of traumatic stress. Though research has predominantly used non-clinical samples or other psychopathologies, it indicates higher social safeness is likely to moderate symptom severity in trauma by facilitating effective social engagement.

In addition, low HRV has been found to correlate with low social safeness in non-clinical samples (Rockliff et al. 2008), and in depressed and anxious populations (Kemp, Quintana, Felmingham, Matthews & Jelinek, 2012). It is likely therefore that as social safeness increases so does HRV by providing the social engagement system environmental feedback (for neuroception) which facilitates effective vagal regulation.

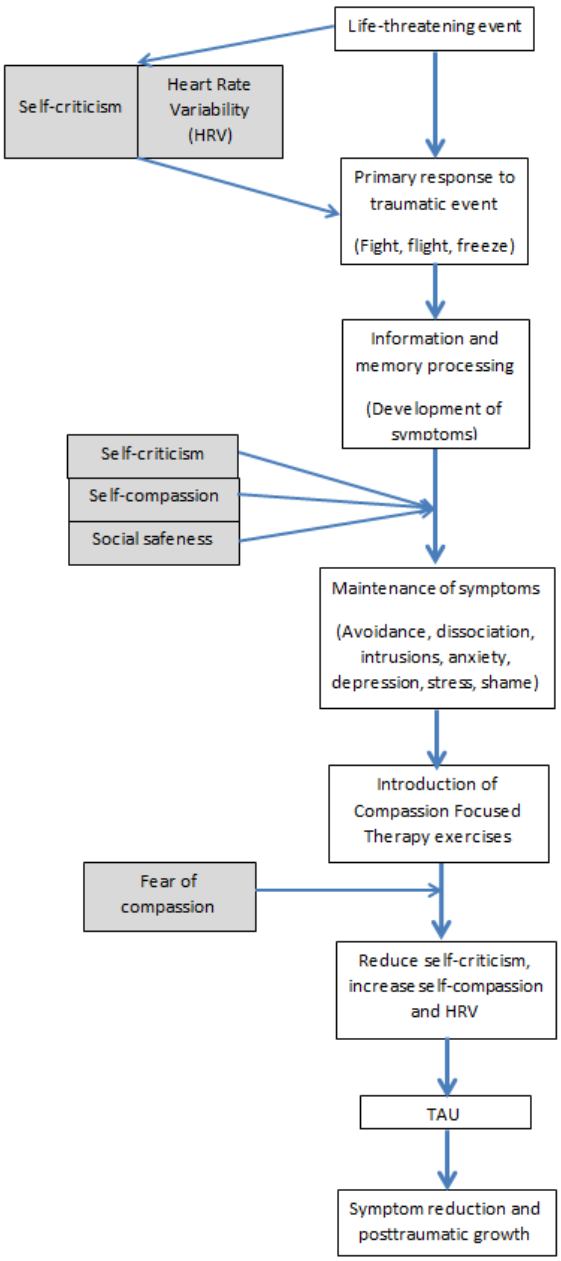

Figure 2. Pathways of mediating and moderating variables.

Interventions

It is argued that early intervention following experience of a traumatic event is important in the trajectory of recovery in individuals (Foa, Keane, Friedman, & Cohen, 2008). However, this is often not accessed by, or available to, many (McManus, et al., 2009). Interventions are often guided by diagnostic labels, with PTSD treatment predominantly focusing on cognitions, exposure and reprocessing of information (National Institute for Clinical Excellence: NICE, 2005) specifically with Trauma Focused Cognitive Behaviour Therapy (tf-CBT; Cahill, Rothbaum, Resick & Follette,

2009) and Eye Movement De-sensitisation and Reprocessing (EMDR; Shapiro, 1989). Treatment evaluations for those without formal diagnosis are limited (Steenkamp, et. al., 2012). Given that this group of people may be at an increased risk for developing clinical PTSD (Mylle & Maes, 2004) earlier intervention even in the absence of a categorical diagnosis may be worthwhile. It is estimated that within veteran populations, 10-25% of those exposed to traumatic events, who don't meet the diagnostic criteria for PTSD still experience traumatic stress symptoms and co-morbidities, yet do not receive treatment (Yarvis & Scheiss, 2008).

Self-criticism may, however be one such barrier for those accessing trauma-focused therapies, particularly those focusing on cognitive and behavioural techniques from which they may find reassurance difficult (Lee, 2005). Indeed, research has demonstrated that highly self-critical people respond less well to standard CBT approaches (Rector, Bagby, Segal, Joffe, & Levitt, 2000) and so exploring alternative options may further facilitate positive outcomes for trauma therapies.

Compassion Focused Therapy (CFT).

Evidence is growing to support the use of CFT (Gilbert, 2005) and its impact on promoting positive mental health and it is increasingly being applied in the field of trauma and related distress (Harman & Lee, 2010). Using CFT's three circles model trauma symptoms can be understood as a product of an overactive threat system which causes increased experiences of anger, anxiety and difficulties feeling safe (Lee & James, 2012). This inhibits the nervous system from regulating arousal levels and associated emotions effectively. CFT in practice aims to help individuals develop the ability to self-soothe in order to regulate the threat system thus reducing perceived experiences of threat (Gilbert, 2005).

An overactive threat protection system may be particularly problematic for those who experience high levels of self-criticism and find it difficult to feel safe and connected with others. For traumatised individuals, this may well be the case and an ineffective or inaccessible soothing system may lead to increased experiences of anxiety, difficulties feeling safe, and may be exacerbated by a fear of compassion (Gilbert, 2009; Lee & James, 2012)

Fear of compassion, prompted by high self-criticism and a sense of underserving, may present as resistance to developing self-compassion because of views of it being 'soft' or of being underserving of this experience (Gilbert et al., 2006). As a result, a high fear of compassion may moderate the impact of CFT intervention on those experiencing traumatic distress. However, it is proposed that developing ways to overcome fears of compassion may be therapeutically important (Gilbert, McEwan, Matos, & Rivis, 2011; Gilbert & Irons, 2004).

Self-help interventions.

Self-help or self-practice ideas are increasingly being developed and tested given constraints on access to psychological services (McCrone, Dhanasiri, Patel, Knapp, & Lawton-Smith., 2008; NICE, 2005). Meta-analyses of self-help interventions have demonstrated some positive effects for depression and anxiety (Lewis, Pearce & Bisson, 2012; Talbot, 2012), as well as for those suffering with PTSD symptoms (Ivarsson et. al., 2014; Sloan, Gallagher, Feinstein, Lee & Pruneau, 2011). Self-practice compassion based interventions are increasingly being researched (McEwan & Gilbert, 2016; Gilbert & Irons, 2004) although not specifically with trauma survivors. Self-help or self-administered therapy, as defined by Newman, Szkodny, Llera and Przeworksi (2011), includes therapist contact solely for assessment purposes.

Recent findings suggest that CFT may act as a helpful adjunct to other psychotherapies such as CBT by enabling development of self-compassion (Beaumont & Hollins Martin, 2015). However, Beaumont and Hollins Martin (2015) highlight the need for additional efficacy research for CFT and NICE (2005) have also recommended development in self-help through RCTs.

This study aimed to explore self-practice CFT for a trauma population. A five-minute daily self-practice CFT intervention and its impact on psychological and physiological mediating and moderating factors associated with trauma was evaluated.

Study Aims

The aims of the study were twofold:

i. To investigate the effectiveness of a modified brief CFT intervention in a pilot-RCT for a trauma population;
ii. To evaluate the intervention regarding its effects on factors associated with the maintenance of trauma symptoms.

It was hypothesised that following the CFT intervention:

i. Symptoms of depression, anxiety, stress and self-criticism will decrease;
ii. HRV, self-compassion and social safeness will increase;

Method

Ethical Approval

The study was granted ethical approval by the host university and the NHS Research and Ethics Committee. In addition, Research and Development Ethical approval was obtained from two local NHS Trusts.

Participants and Procedure (see Figure 3.)

All participants had been referred for psychological input for trauma-related distress and were considered to be experiencing some PTSD symptoms. Eligibility was met if participants were accepted onto the waiting list for treatment at the targeted specialist trauma service for adults in the East Midlands, UK, and could understand written and spoken English. The referral criteria for the service does not require a formal diagnosis of PTSD but accepts those who report having experienced a traumatic event(s) and are experiencing ongoing traumatic stress symptoms. The service operates a waiting list of up to 18 weeks and urgency of treatment is evaluated on a case by case basis of clinical need. The CFT practice was not a replacement for trauma specific therapies and given that many existing services now operate waiting lists (Mind, 2010) such interventions may support individuals during waiting times.

Therapists at the trauma service were provided with detailed information about the research. Participants who consented to take part were allocated to the CFT or waiting-list condition using blocked randomisation (Saghaei, 2004). Block sizes of two and four were utilised to allocate participants on a one-to-one ratio between the two intervention

arms. This allowed an increased likelihood of having comparable group sizes, controlling for the availability of participants over time (Schulz & Grimes, 2002). All participants had their HRV measured at each of three appointments with the researcher where the questionnaires were also completed. Questionnaires were answered in the same order for all participants across appointments.

Participants were instructed to practice the CFT intervention script over a three-week period on a daily basis. Record sheets were provided to encourage participants in noting when they practiced, how long for, and any feedback related comments. All participants were informed they could continue practising following completion if they wished. Following the intervention, participants provided feedback on their practice. Participants in the immediate intervention arm were asked at six weeks if they had continued to practice the exercises. The measures completed at each appointment are described in table. 5.

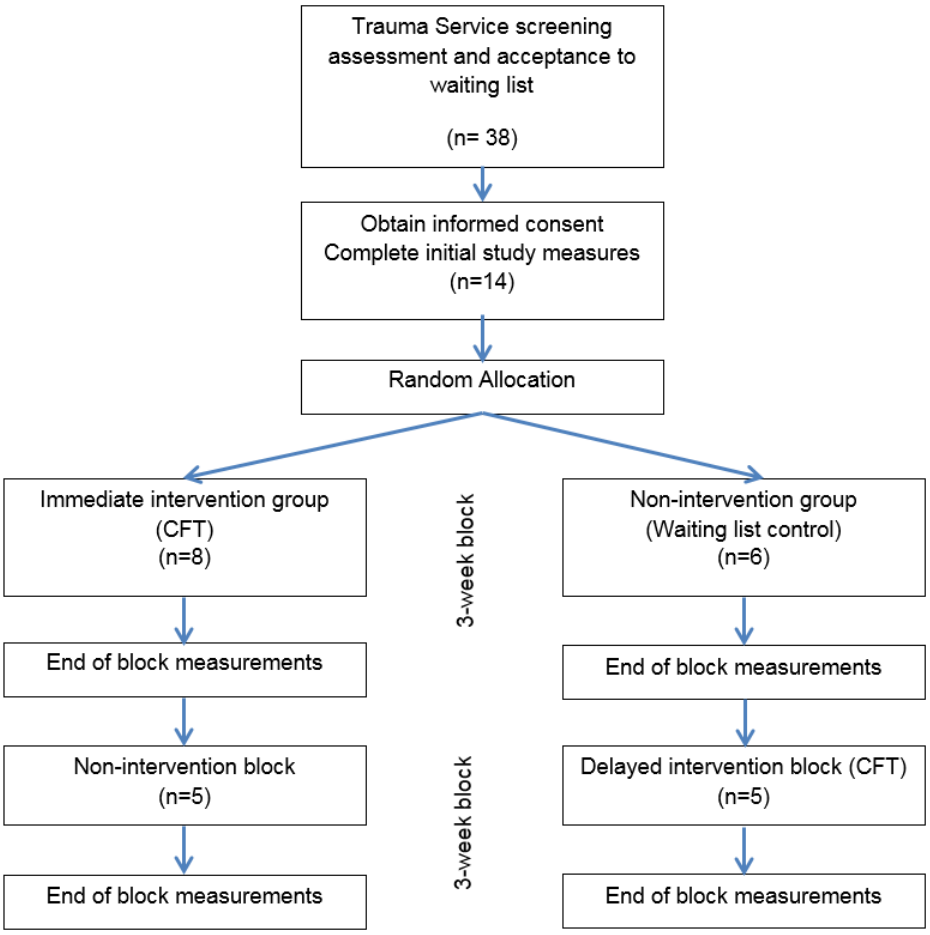

Figure 3. Procedure .

Table 5. Measures completed (see appendix A for sample items for each measure)

Name of Measure (Authors)	***Description of Measure***	***Additional Information***
Depression, Anxiety, and Stress Scale *(DASS-21; Lovibond & Lovibond, 1995).*	Self-report measure of negative emotional states of depression, anxiety and stress. Provides subscale score, and total score. Rated on a four-point Likert scale ranging from 'never' to 'almost always'	Valid measure of general psychological distress (Henry & Crawford, 2005). Good reliability; α = .82-.97 across the subscales (Osman et al. 2012) and sensitivity to change (Page, Hooke & Morrison, 2007).
Impact of Events Scale – Revised *(IES-R; Weiss & Marmar, 1997)*	22-item measure of avoidance, intrusion and hyperarousal. Provided subscale and total score. Rated on a five-point Likert scale ranging from 'not at all' to 'extremely'. Scores on the subscales are averaged.	Good reliability (intrusion α = 0.87, avoidance α = 0.85 and hyperarousal α = 0.79)
Psychological Well-being – Post-Traumatic Change Questionnaire *(PWB-PTCQ; Regel & Joseph, 2010)*	18-item self-report questionnaire assessing perception of change in psychological well-being after traumatic events. Ratings on a Likert scale from 1 ("much less so now") to 5 ("much more so now").	Satisfactory internal consistency over three samples (α = .87, .95 and .93; Joseph et al. 2012). The scale correlates with measured changes over time (*r* = .41) (Joseph et al. 2012).

Name of Measure (Authors)	***Description of Measure***	***Additional Information***
Forms of Self-Criticising/Attacking & Self-Reassuring Scale *(FSCRS; Gilbert, Clarke, Hempel, Miles & Irons, 2004).*	22-item self-report measure of self-criticism and the ability to self-reassure when things go wrong. Subscales 'inadequate-self' and 'hated-self' (self-criticalness), and 'self-reassure'. Rated on a Likert scale from 0 ('not at all like me') to 4 ('extremely like me').	α = .90 for inadequate self and .86 for hated self and reassured self (Gilbert et al. 2004).
Fears of Compassion Scale: Scale 3 – Expressing kindness and compassion towards yourself *(FOC; Gilbert et al., 2011).*	15 items measuring fears of self-compassion. Rated on a Likert scale from 0 ("don't agree at all) to 4 ("completely agree")	Demonstrated good reliability (Gilbert, et al., 2011) with both students (α = .92) and therapists (α = .85).
Self-Compassion Scale: Short Form *(SCS-SF; Raes, Pommier, Neff & Van Gucht, 2011).*	12-item measure of self-compassion, rated on a Likert scale from 1 ("almost never") to 5 ("almost always"). A total mean self-compassion score is computed	Excellent correlation with the long form (SCS: Neff, 2003) (*r* = .98 in an English sample). Demonstrates good internal consistency (α =.86).
Social Safeness and Pleasure Scale *(SSPS, Gilbert, et al. 2009).*	11-item questionnaire developed to measure the extent to which people experience their social worlds as safe, warm and soothing. Rated on a Likert scale from 0 ("almost	High α = .92 (Gilbert at al. 2009). Increasing experiences of social safeness may be facilitated by the CFT practice (Kelly, et al.,

Name of Measure (Authors)	*Description of Measure*	*Additional Information*
	never") to 4 ("almost all the time")	2012)
Heart Rate Variability (HRV) *Polar RS800CX Heart Rate Monitor (HRM)*	Measures HRV by wearing a watch and chest strap. Measurements provided were for various time and frequency domains of HRV.	Excellent agreement with electrocardiogram (ECG) measures (Gamelin, Baquet, Berthoin & Bosquet, 2008; Sandercock, et al. 2004; Weippert et al. 2010).

Intervention

Participants were provided with an amended CFT script (based on an earlier phase of this research project), comprising of a definition of compassion, its benefits and instructions for practising compassionate exercises (see Appendix C for intervention script). The compassion exercises were (i) soothing rhythm breathing; (ii) practising saying hello in neutral and friendly voice tones and facial expressions; (iii) compassion imagery; (iv) focusing compassion on others; (v) focusing compassion on self and; (vi) focusing compassion on challenges. Each exercise was followed by a suggested time to spend practising each one, with the exercises totalling five minutes. Participants could use either the audio or written versions. They could choose what time of day they practised and were instructed that they could practice for longer than the required five minutes if they wished.

Analysis

Analysis was conducted using IBM SPSS Statistics version 21 and the data were screened for normality of distribution and for any outliers. Two-way mixed ANOVAs were used to explore the effects of group (immediate or delayed intervention) on changes (increases or decreases) in symptoms of depression, anxiety, and stress. Time (pre, mid, post) was used as the within-subjects variable with group condition as the between-subjects variable. These analyses were repeated for each sub-scale of the DASS-21 and for each of the remaining independent variables. Bonferroni corrections were applied in to adjust for multiple comparisons. Significant findings are summarised.

HRV analysis was conducted in accordance with Task Force Guidelines related to short HRV measurement (Task Force, 1996). Of the recorded times of HRV, five minute selections were analysed. These were taken from the middle of recording times to eliminate as far as possible noise interference at the beginning and end, and to allow for participants to have completed some questionnaires and potentially felt less anxious that at the start of appointments (Frustaci, et. al., 2010). rMSSD was interpreted rather than the pNN50 due to this being considered more a mathematically robust measure (Nunan, et al., 2010). Whilst Task Force Guidelines (1996) recommends manual editing of R-R interval data, it is considered that this is likely out of date for modern technologies and

their associated analysis software and therefore this was not conducted for the current data set (Nunan, et al., 2010). Instead, automatic error correction (a tool provided by the Polar ProTrainer5 software), corrected to a "moderate" degree for each set of data. For some reports, no corrections were required. Low frequency to high frequency ratios (LF:HF) were interpreted to offer analysis of parasympathetic activity (lower ratios are indicative of more parasympathetic activity and thus lower HRV and less effective regulation of the nervous system).

Results

Four participants (28.57%) dropped out of the study due to external events impacting on their ability to engage. Therefore the final sample consisted of 10 (four female; six male) adult survivors of traumatic events, including road traffic accidents (RTA), active military service, traumatic bereavement, domestic violence, sexual abuse, and violent assaults. Attrition was from both the immediate (n=3) and the delayed (n=1) conditions. Only completers' data were included in the analyses.

Participants had a mean age of 47.10 years (SD = 12.57 years) ranging from 28 to 65 years. All were White British and the average time from their traumatic experience to their initial assessment for the trauma centre was 73.7 months, (range 1 to 23 years). HRV data were available for eight of the 10 participants due to recording errors for two participants. All participants' data were available for all other measures.

Descriptive statistics of the overall and group samples are provided in Table 6. There were no significant differences in the ages or gender splits between the two groups, nor in the majority of the initial assessment measures suggesting reasonably effective randomisation of participants to condition. However t-tests indicated that there were significant differences between initial IES-R avoidance scores (t = -2.613, p =.047; equal variances not assumed) with the delayed intervention group demonstrating higher scores on this subscale of the IES-R.

Table 6. Descriptive statistics by overall sample and group (completers)

Condition	Age (years)		Time since trauma (months)	
	M	*SD*	*M*	*SD*
Immediate (*n*=5)	43.60	10.16	91.4	114.80
Delayed (*n*=5)	50.60	14.89	56.00	53.28
Overall Sample (*n=10)*	47.10	12.57	73.70	86.41

Descriptive statistics of the primary outcome measure, (DASS-21) total scale scores are provided in Table 7.

Table 7. Mean DASS-21Total scores at pre, mid and post intervention (completers)

Condition	Pre		Mid		Post	
	M	*SD*	*M*	*SD*	*M*	*SD*
Immediate (*n*=5)	41.80	7.46	37.40	14.52	29.4	12.26
Delayed (*n*=5)	42.80	10.71	38.2	11.23	36.40	11.10

Table 8 shows the descriptive statistics of the main measurements of HRV for whole sample excluding the extreme outlier.

Table 8. Descriptive data for HRV information.

HRV	Pre		Mid		Post	
	M	*SD*	*M*	*SD*	*M*	*SD*
Mean R-R (ms)	722.29	106.49	761.29	108.24	767.43	116.92
SDNN (ms)	31.49	8.79	30.63	10.73	30.60	9.70
rMSSD (ms)	14.80	5.28	12.27	5.54	14.24	6.43
LF (ms^2)	772.43	106.49	233.45	128.18	316.32	211.61
HF (ms^2)	112.45	64.39	64.46	50.14	94.75	107.41
LF: HF (%)	428.17	230.39	520.53	308.64	604.27	449.72

Statistical analysis

There were several outliers across all measures with the exception of the FOC. One participant's scores presented as an extreme outlier for the majority of the HRV measurements in the immediate condition. Inclusion of this participant's data impacted on the normality of the data. Exclusion of this participant from the HRV analysis led to the data being normally distributed, as assessed by Shapiro-Wilk's test of normality ($p > .05$). The data also violated assumptions of normal distribution for the DASS-21 stress, anxiety and total scores, for the inadequate self FSCRS scale, for the avoidance and intrusion IES-R subscales, on the PWB-PTCQ scores and on the FOC scale, as assessed by Shapiro-Wilk's test of normality ($p < .05$). There was homogeneity of variances for all measures except for the IES-R avoidance scale, the SPSS scale and the HF measure of HRV, as assessed by Levene's test of homogeneity of variance ($p < .05$). Mauchley's test of sphericity indicated these assumptions were met for the two-way interaction, for all measures apart from the hated self FSCRS subscale and the PWB-PTCQ.

The interaction effect between the group condition and time on total DASS-21 scores was not statistically significant, $F(2, 16) = .412$, $p = .669$, partial $\eta^2 = .049$. Analysis of the main effect of time was also not statistically significant, $F(2, 16) = .2.933$, $p = .082$,

partial η^2 = .268. Main effect of group also demonstrated non-significant findings, $F(1, 8) = .269$, $p = .618$, partial $\eta^2 = .033$.

Interaction effects. There were no significant interaction effects between group and time for any of the scales or their relative subscales or measures of HRV.

Main effects. Analyses of the main effects for time and the main effect for group were performed. No significant main effects were found with regards to the DASS-21 anxiety and stress subscales and total scores, the reassure-self (FSCRS subscale), the SCS-SF, SSPS, PWB-PTCQ, FOC or HRV measurements. Findings reported below are of significant main effects.

A main effect of time was found for the DASS-21 depression subscale, $F(2, 16) = 4.729$, $p = .024$, partial $\eta^2 = .372$. A main effect of time was found for the IES-R total scores, $F(2, 16) = 17.147$, $p < .00$, partial $\eta^2 = .682$. Main effects of time were also found for avoidance $F(2, 16) = 5.671$, $p = .014$, partial $\eta^2 = .415$, intrusion $F(2, 16) = 13.503$, $p < .00$, partial $\eta^2 = .628$, and hyperarousal scores $F(2, 16) = 7260$, $p = .006$, partial $\eta^2 = .476$. A significant main effect of time was also demonstrated for the FSCRS inadequate-self scores, $F(2, 16) = 7.845$, $p = .004$, partial $\eta^2 = .495$, and hated-self scores, $F(2, 16) = 7.246$[6], $p = .020$, partial $\eta^2 = .475$.

A statistically significant main effect of group was found for IES-R avoidance subscale scores ($F(1, 8) = 7.773$, $p = .024$, partial $\eta^2 = .493$).

Pairwise comparisons. Following the analyses of main effects, pairwise comparisons were explored where reported 95% confidence intervals and *p*-values are Bonferroni-adjusted.

The unweighted marginal means of IES-R total scores for pre, mid, and post-intervention measurements were 63.9 (*SE* = 3.44), 55.00 (*SE* = 4.23), and 46.50 (*SE* = 5.38), respectively. Pre-intervention (T_1) was associated with a mean IES-R total score 8.90, 95% CI [.437, 17.36] points higher than mid-intervention (T_2), a statistically

[6] Greenhouse-Geisser statistics were used due to violation of sphericity

significant difference, p = .039 and 17.40, 95% CI [6.94, 27.86] points higher than post-intervention (T_3), p = .003. Mid-intervention (T_2) was associated with a mean IES-R total score 8.50, 95% CI [.764, 16.24] points higher than post-intervention (T_3), p = .032. These results demonstrate significant reductions in IES-R total scores regardless of delayed or immediate CFT intervention.

The unweighted marginal means of IES-R intrusion scores for pre, mid, and post-intervention measurements were 3.08 (*SE* = .236), 2.76 (*SE* = .319), and 2.14 (*SE* = .325), respectively. Pre-intervention (T_1) was associated with a mean IES-R intrusion score .938, 95% CI [.351, 1.524] points higher than post-intervention (T_3), a statistically significant difference, p = .004. Mid-intervention (T_2) was associated with a mean IES-R intrusion score .625, 95% CI [.040, 1.210] points higher than post-intervention (T_3), p = .036. These results demonstrate significant decreases in IES-R intrusion scores regardless of delayed or immediate CFT intervention.

The unweighted marginal means of IES-R hyperarousal scores for pre, mid, and post-intervention measurements were 3.13 (*SE* = .223), 2.58 (*SE* = .250), and 2.32 (*SE* = .283), respectively. Pre-intervention (T_1) was associated with a mean IES-R hyperarousal score .817, 95% CI [.122, 1.511] points higher than post-intervention (T_3), a statistically significant difference, p = .023. These results demonstrate significant decreases in IES-R hyperarousal scores regardless of delayed or immediate CFT intervention.

The unweighted marginal means of FSCRS inadequate-self scores for pre, mid, and post-intervention measurements were 3.24 (*SE* = .238), 3.07 (*SE* = .222), and 2.42 (*SE* = .232), respectively. Pre-intervention (T_1) was associated with a mean FSCRS inadequate-self score .822, 95% CI [.224, 1.419] points higher than post-intervention (T_3), a statistically significant difference, p = .010.

The unweighted marginal means of IES-R avoidance scores for immediate and delayed intervention groups were 1.88 (*SE* = .173), and 2.57 (*SE* = .173), respectively. Immediate CFT was associated with a mean IES-R avoidance score -.683, 95% CI [-1.25, -.118] points lower than delayed CFT, a statistically significant difference, p =

.024. These results demonstrate significant differences in IES-R avoidance scores regardless of time with the immediate CFT group consistently scoring lower on this scale than the delayed CFT group.

Discussion

CFT has been demonstrated in the literature to impact positively on factors associated with the maintenance of trauma symptoms (Breslau, 2002; Gilbert, 2010; Pietrzak, et. al., 2011). This study adopted a pilot-RCT design to explore the impact of a self-practice CFT intervention for clients experiencing traumatic stress, extending an earlier study which tested the feasibility and acceptability for a brief self-practice CFT intervention with a small clinical sample of community clients (Rycroft, et al., draft manuscript). The effects of the CFT self-practice intervention on measures of depression, anxiety and stress, as well as additional factors associated with ongoing traumatic stress were explored. At this stage, although changes were noted to occur in the anticipated direction for hypotheses one (decreased depression, anxiety, stress and self-criticism) and hypothesis two (increased HRV, self-compassion and social safeness), these were non-significant. Moderation analyses were not able to be conducted on the data to answer hypothesis three (high FOC and/or self-criticism will moderate the effects of CFT).

Previous research with a non-clinical sample found much greater improvements on the DASS-21, SCS, and FSCRS following self-practice of an earlier version of the CFT intervention (McEwan & Gilbert, 2016). In addition, a feasibility study with a clinical sample (Rycroft et. al., draft manuscript) demonstrated significant large effects of the CFT intervention on the DASS-21; such findings were not replicated in the current study.

In the current sample, it was noted that levels of HRV observed at the pre-intervention measurement (measured by the SDNN) were lower than that of a healthy community sample (Rockliff et al., 2008). This fits with the literature that traumatised individuals may have lower levels of HRV than healthy populations (Lee & Theus, 2012) and perhaps offers some consideration as to this being a hindrance for therapeutic benefits in relation to self-practice of CFT. As such, evidence from the pilot-RCT does not

demonstrate significant improvements in factors associated with maintenance of trauma symptoms. However, some caution should be adopted when concluding from these results due to some of the study limitations.

Study Strengths

The current study has offered early exploration of self-practice interventions, which acknowledges recent NICE recommendations (NICE, 2005) and offered a first study of self-practice CFT in a clinical sample of trauma clients.

Reductions were demonstrated for symptoms of trauma relating to intrusion, avoidance, and hyperarousal over time, although this was not specific to intervention group. This may suggest the best predictor of change is reductions on the index measure of traumatic stress (IES-R). This may offer support for the intervention being effective as an adjunct to trauma-specific therapies. By reducing symptoms of traumatic stress following the CFT intervention, individuals may be more able to make use of therapeutic interventions by way of a phase-based approach (Cloitre, et. al., 2011). Reduced avoidance and hyperarousal may be particularly important for this (Neff, Rude, & Kirkpatrick, 2007).

Limitations

The sample size for the study is small and this is likely to have impacted on the results. Although the power calculations were based on the effects of practising the CFT intervention over a two-week period in the feasibility phase (Rycroft, et al., draft manuscript), this was not replicated. Further data will allow adequate power to be achieved and offer greater insights in to the impact of the intervention and additional suggestions have been made as to how this informs future research.

In addition, baseline measures, although planned for completion by clinicians at screening assessments, were not captured for participants. This may be impacted by the service's reliance on visiting therapists comprising a limited core team, and reminders for therapists to administer all questionnaires may have been inconsistent. As a result, it is difficult to reliably assess whether being accepted onto a waiting list for therapy has any immediate positive effects on any of the measures for this sample. This could be

addressed in future studies by targeting psychological services with larger teams and more established assessment protocols for baseline assessments to be better incorporated.

Furthermore, participants were required to practice the CFT intervention on a daily basis for a minimum of five minutes for three weeks. Whilst data about their practice was collected post-intervention, some participants may have over-reported their practice times and frequencies if responding in a socially desirable way. However, it appeared that many participants acknowledged if they had not practiced the intervention on some days and commented on exercises they found difficult or avoided. Variations in intervention adherence are difficult to measure accurately and may be a complicating factor. Some participants did indicate external events which may have impacted on their ability to engage with practice. Such difficulties may have impacted on responses on the various assessment measures.

Future directions

This research offers a starting point to develop the intervention research in the field of CFT and self-practice. Building on positive findings from a non-clinical and a small clinical community sample, this study demonstrates some changes in the anticipated directions. Continuing to collect data for this sample may therefore offer more scope for identifying significant effects of the intervention and address the need for an adequately powered study with a clinical population. Participants are continuing to be recruited in order to meet minimum power requirements. In addition, data following trauma-focused interventions for the sample will contribute to a follow up study looking at trauma therapy outcome measures for this population. This will enable further exploration of whether engaging in a self-practice waiting list intervention demonstrates effects on post-therapy outcomes for this clinical sample.

Secondly, whilst a waiting-list control group offers the ability to look at group differences, future research would benefit from comparing the CFT intervention with an active control group. This would enable clearer comparisons specifically between CFT material and an alternative therapeutic model. This would allow further conclusions as to whether changes can be considered intervention-specific.

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Extended Paper

Background

The aim of the background section of this extended report is to give an overview of research regarding traumatic stress and compassion focused therapy (CFT). This will consider definitions of traumatic stress and overlaps with posttraumatic stress disorder (PTSD), prevalence and co-morbidity, models of trauma, the CFT model, factors influencing traumatic stress with consideration as to the limitations of the current literature. Treatment and its current evidence base for trauma will also be briefly reviewed.

Trauma and PTSD

Definitions

PTSD may be diagnosed when a stressor has been experienced and symptoms from four main clusters are present; intrusion, avoidance, negative alterations in cognitions and mood, and changes in arousal (American Psychiatric Association; APA, 2013). Consideration is also advised regarding symptom-duration, functional significance of the symptoms and exclusion of alternative explanations. Specification of immediate or delayed onset is included as is dissociation[7] as an additional sub-type of PTSD (APA, 2013). Common symptoms of PTSD include elevated fear responses, startle reactions, traumatic nightmares, negative thoughts about the self and the world, and avoidance (APA, 2013; Craske et al. 2009; Friedman, et al. 2011). Trauma survivors may also experience hypersensitivity to threat-related stimuli (Schönenberg & Abdelrahman, 2013), as well as additional distress in the form of depression and anxiety (Friedman et al. 2011). Whilst historically, PTSD has been seen as primarily underpinned by anxiety, fear and helplessness (DSM-IV-TR; APA, 2000), recent findings suggest that shame can be an underlying feature of ongoing traumatic distress (Holmes, Grey & Young, 2005). Although, shame was described as a factor in PTSD in earlier theories of trauma (e.g. Horowitz, 1983), research has focused predominantly on anxiety in line with the

[7] Dissociation can be considered as an adaptive strategy to function through a traumatic event, often referred to as a sense of leaving one's body and becoming a spectator of an event (Van der Kolk, 2007), or compartmentalisation of an experience (Van der Kolk, Van der Hart, & Marmar, 2007). This can become problematic in daily life if it continues following the trauma.

positioning of PTSD as an anxiety disorder within diagnostic classification systems.

Despite the framework for diagnosing PTSD provided by the DSM-5 (APA, 2013) and previous versions, questions have been raised as to whether trauma should be defined by characteristics of the event itself, or the impact it subsequently has on the individual, hence the phrase 'traumatic stress' refers to the event as well as the experience of being traumatised (Kaminer & Eagle, 2010). It has been argued that the simplicity of a label of PTSD does not adequately describe the complex nature of individual responses to trauma and the more subtle interactions between psychological and biological processes which result in varying presentations (Nemiah, 1995; Van der Kolk, McFarlane & Weisaeth, 2007). Indeed, trauma may be considered as an extreme form of stress; however it is likely a more complex picture, influenced by more subjective experiential factors than simply the nature of an event (Christopher, 2004). As such, it is important to consider what subjective factors may influence individuals to experience traumatic stress symptoms and subsequently engage in or develop maladaptive responses. [See later sections for further discussion].

Despite these conceptual challenges, the category of PTSD can be a useful framework for investigating the phenomena, the associated risk factors, developmental trajectories, and implications for treatment. Subjective experiences of traumatic events are no longer required for diagnosis (Jones & Cureton, 2014). However it remains one of the most controversial diagnoses in relation to prevalence, clinical utility and symptomatology (Brewin, Lanius, Nova, Schnyder, & Galea, 2009) and the categorical definitions do not allow for exploration of what may be considered sub-clinical or sub-threshold levels of symptoms, (Weiss et al., 1992).

There is growing literature around the concept of 'partial' or 'subclinical' PTSD (Mitchell et. al., 2012; Schnurr, 2014). Definitions include experience of at least one symptom in each category of DSM PTSD criteria (Stein, Walker, Hazen, & Forder, 1997; Yarvis & Scheiss, 2008). Definitions however are varied, 'Sub-

threshold', 'subclinical', and 'partial PTSD' are phrases which may be attributed to individuals who experience symptoms of traumatic stress and present with notable impairments in their daily functioning but do not fulfil the diagnostic requirements for PTSD (McLaughlin, et. al., 2015; Naylor, et. al., 2013). This can impact on their ability to access trauma-focused therapy and can result in individuals' distress being neglected (Cukor, Wyka, Jayasinghe, & Difede, 2010; Erickson, Hedges, Call, & Bair, 2013). This is important given findings that subclinical PTSD may increase the risk of developing full diagnostic PTSD (Mylle & Maes, 2004; Cukor, et. al., 2010) with meta-analysis findings suggesting subclinical PTSD may put someone up to 11 times more at risk of delayed onset clinical PTSD (Smid, Mooren, van der Mast, Gersons, & Kleber, 2009). For the purposes of consistency, the term subclinical will be used hereafter, but will reflect the interchangeability applied in the wider literature.

Subclinical PTSD is complicated by the varying definitions which may include; meeting at least one symptom of DSM criterion (Breslau, Lucia, & Davis, 2004; Pietrzak, et. al., 2012; Stein, Walker, Hazen, & Forder, 1997). This lack of clarity of definitions offers support to the view of PTSD as a dimensional continuum rather than a categorical phenomenon (Broman-Fulks et al., 2006; Erickson, et. al., 2013).

Prevalence

The development of PTSD following a traumatic experience affects a significant number of individuals, with lifetime prevalence rates for European countries ranging from 0.56% - 6.67% (Wittchen et al., 2011). A recent estimate from the Adult Psychiatric Morbidity Study (APMS) from 2007, suggested a UK lifetime prevalence around 3% (McManus, et al., 2009). However this may no longer be accurate given that many more people are likely to have experienced traumatic events and developed PTSD since this data was presented. In addition, the World Health Organisation (WHO; Kessler & Ustun, 2008) found lifetime prevalence rates over 27 countries ranging from 0.3% (China) to 6.1% (New Zealand). It is important to contextualise findings and note that there are variations in the methodological and sampling approaches utilised by such

prevalence studies and not all delineate types of traumatic events within this data.

The varying events or experiences which may be considered traumatic and then lead to the development of posttraumatic symptoms are vast and therefore it is difficult to predict an accurate umbrella prevalence rate which can account for the differences between trauma-type and populations (Brewin, Andrews, & Valentine, 2000). For example, research post-September 9/11 found prevalence rates of PTSD for rescue workers ranged from 6.2% to 21.2% (Perrin, et al., 2007), and rates for community and veteran samples were approximated at 2.3% and 34.4% respectively (Seal, et al., 2008) and 12-month prevalence rates for 5.4% in a community sample of Americans and 30.3% for veterans (Miller, et. al., 2013). The data available for general prevalence rates may therefore be skewed by a focus on specific individual trauma types which can result in potential groups of traumatised individuals being neglected in the research (Korte, Allan, Grox, & Acierno, 2016). As such, prevalence rates should be taken as approximations.

With regards to subclinical levels of posttraumatic stress symptoms, there are relatively fewer studies of this population (Steenkamp et al., 2012). Some estimates of prevalence are similar between subclinical and clinical PTSD with one of the earliest and influential studies (National Vietnam Veterans Readjustment Study; Kulka et al., 1998), suggesting a lifetime prevalence of subclinical PTSD of 22.5% in men and 21.2% in women compared to clinical PTSD in 30.9% of men and 26.0% of women (Weiss et al., 1992). However these rates are based on the now outdated Diagnostic and Statistical Manual – Version Three – Revised (DSM-III-R; American Psychological Association [APA] 1987). In addition, exploration of a sub-sample of participants from the National Comorbidity Survey-Replication (NCS-R; Kessler, Chiu, Demler, Merikangas, & Walters, 2005) survey found prevalence of subclinical PTSD to range from 9.8% to 11.6% depending on which diagnostic criteria were used (Mitchell et al., 2012). More recently, prevalence of subclinical PTSD has been reported to be between 6.6% and 27.6% (Breslau et. al., 2004; Pietrzak,

Goldstein, Southwick, & Grant, 2011). However the large differences in these figures are likely to be influenced by the relative samples studied; with Breslau and colleagues (2004) using a sample from Detroit, USA and Pietrzak and colleagues (2011) basing their study are a national sample. A core difficulty with establishing accurate prevalence rates for subclinical PTSD is the many ways to define it, and no consensus on how to do this (Schnurr, 2014; Yarvis & Schiess, 2008). Nevertheless, such figures are indicative of a significant number of individuals who may be overlooked as a result of not receiving diagnosis of PTSD (Zlotnick, Franklin, & Zimmerman, 2002).

Gender differences

Gender differences may impact on overall prevalence rates, with many studies indicating women are more likely to experience PTSD than men, even when trauma type is controlled for (Foa, Keane, Friedman, & Cohen, 2008; Kessler, Sonnega, Bromet, Hughes, & Nelson, 1995) and despite indication that women are less likely to be exposed than men to traumatic events (Tolin & Foa, 2008). These findings were supported in a recent national study of U.S. adults (Pietrzak et. al. 2011) reporting women having higher prevalence rates of PTSD and subclinical PTSD than men (PTSD; 8.6%/4.1%, subclinical PTSD; 8.6%/4.5% for women/men respectively). However, often these studies do not control for all trauma types and may exclude assault-related (including sexual) traumas (Zoladz & Diamond, 2013) and when this is accounted for, findings often do not support the gender difference debate (e.g. Grieger, Waldrep, Lovasz, & Ursano, 2005; Maguen et. al., 2009).

Research has demonstrated differences in trauma types most commonly associated with men or women, with women reporting higher prevalence of partner abuse and sexual traumas, and men reporting higher incidences of physical assault, combat-related traumas and witnessing of traumatic events (Mills, et. al., 2011; Tolin & Foa, 2008). Little research has explored gender differences for subclinical PTSD, although Christiansen & Hansen (2015) investigated gender differences in a Danish sample. They found that 24.9% of

women and 7.7% of men in the sample had subclinical PTSD, demonstrating a significant gender difference.

In terms of gender differences relating to treatment, Wade and colleagues (2016) reported that women had better outcomes in relation to symptom reduction than men at post-intervention and at short term follow up. Previously Watts and colleagues (2013) had demonstrated larger effects in psychotherapies where the recipients of treatment were predominantly women, although this study utilised indirect analyses methods, in that they did not evaluate only groups which had included a mix of gender. However the Wade et. al. (2016) meta-analysis was limited in relation to the variability in specified treatments evaluated, and variable quality in the studies included (data was inadequately powered to assess the potential for gender to modify intervention effects). However, they highlight the potential need to explore gender differences in response to treatment for PTSD.

Co-morbidity

Using data from the NCR-R, studies have found associations between PTSD and suicidal ideations and attempts (Cougle, Keough, Riccardi, & Sachs-Ericsson, 2009; Kessler, Chiu, Demler, Merikangas, & Walters, 2005). Both PTSD and subclinical traumatic stress symptoms have been found to frequently occur along with other diagnoses (Adshead, 2000; Pietrzak, et. al., 2011). Regarding clinical PTSD, it is commonly comorbid with anxiety, depression and substance misuse (Breslau, 2002; Dadic-Hero, Toric, Ruzic, Medved, & Graovav, 2009; Mayou, Bryant, & Ehlers, 2001) and similarly with subclinical PTSD demonstrate comorbidity with depression, phobias, generalised anxiety and alcohol use (Asmundson, Stein, & McCreary, 2002; Kessler, et. al., 2005; Pietrzak, et. al., 2011b).

Findings have indicated similar levels of comorbidity between clinical and subclinical PTSD veterans for physical health concerns (Fetzner, McMillan, & Asmundson, 2012), increased experiences of anger and aggression (Jacupak, et. al., 2007) and in general populations, those with subclinical PTSD were

found to be more likely to meet criterion for borderline, schizotypal or narcissistic personality disorders compared to trauma controls (Pietrzak, et. al., 2011). Subclinical PTSD has also been associated with significantly higher risk for suicidality than those with diagnostic PTSD (Marshall, et al., 2001). However there are huge disparities between estimates (Spinhoven, Penninx, van Hemert, de Rooij, & Elzinga, 2014) and it is not always clear which may present as the primary issue, complicating the ability to separate out some symptoms (Licanin & Redzic, 2002). At times this may be complicated by the difficulties with defining subclinical PTSD (Cukor et. al., 2010; Yarvis & Schiess, 2008). Despite the limitations of the current evidence around subclinical PTSD, those with subclinical levels of symptoms report problems with alcohol use (Boscarino, Adams, & Galea, 2006) and sickness absence from work (Breslau, et. al., 2004) indicating factors which impact on the cost of mental health to society (McCrone, Dhanasiri, Patel, Knapp, & Lawton-Smith, 2008).

Risk factors

Much of the research into risk factors have focused on those indicating individuals developing PTSD and are often discussed in terms of pre-trauma (e.g. demographic factors, psychiatric and medical history), peri-trauma (type and intensity of events) and post-trauma (perceived threat, biological and emotional response, recovery environment) risk factors (Duke & Vasterling, 2005; Pietrzak et. al., 2012).

The argument for gender as a risk factor (stemming from the studies exploring differences in prevalence rates) is widely debated. It is argued that it may be a greater risk factor specifically in relation to assault-based traumas and is biased toward the higher prevalence of women experiencing this trauma type (Creamer, Burgess, McFarlane, 2001). However even this notion has been debated; when accounting for history of assault, women were no more likely to develop PTSD following an assault (Cortina & Kubiak, 2006). In addition, Vogt et. al. (2011) found that women were as resilient as men in their response to combat-related stress, with men being more likely to develop substance abuse related difficulties following combat stress. Additional factors, perceived danger

and trait anxiety, have recently been demonstrated to moderate the impact of gender (Spindler, Elklit, & Christiansen, 2010).

Risk factors for subclinical PTSD suggest that symptoms may be associated with prior trauma exposure, psychiatric history and their environment during recovery (Koenen, Stellman, Sommer, & Stellman, 2008; Pietrzak, et al., 2012) Schnurr et. al., (2003) found that Vietnam veterans who developed clinical PTSD scored higher on a social introversion scale prior to their military service than those who developed subclinical PTSD. Greater exposure to occupational trauma following an event has also been considered a risk factor for PTSD, and a history of trauma exposure a risk for subclinical levels (Cukor, et. al., 2010).

Research, including meta-analyses, has also identified social support as a key risk factor for PTSD (Brewin, et al., 2000; Guay, Billette, & Marchand, 2006; Ozer, Best, Lipsey, & Weiss, 2003). This has been particularly considered in the context of initial development of PTSD, but more recently in relation to ongoing PTSD maintenance (Laffaye, Cavella, Drescher, & Rosen, 2008). Indeed, for veterans a recent study found that limited social support from the community, in addition to lack of availability of secure relationships, and excessive worry, mediated the relationship between PTSD and poor social functioning (Tsai, Harpaz-Rotem, Pietrzak, & Southwick, 2012). It has been suggested that negative social support is generally more strongly related to PTSD than positive interactions (Charuvastra & Cloitre, 2008).

Physiological markers have also been indicated as potential risk factors, including those with PTSD being found to have lower Heart Rate Variability (HRV: see section ‘HRV) at rest, than healthy controls (Cohen et. al., 2000). A recent twin study demonstrated that current PTSD was inversely associated with low HRV, with twins with PTSD demonstrating 49% lower levels of low-frequency HRV than their brothers with no PTSD (Shah, et. al., 2013). The association with PTSD and low HRV mostly disappeared when current PTSD was accounted for, suggesting that recovery from PTSD may indicate recovery in HRV activity.

Risk factors specific to subclinical PTSD are less clear. However there is some suggestion that type and frequency of trauma increased the risk for subclinical PTSD, as it does for diagnostic PTSD, with sexual abuse, and particularly early exposure, increasing risk of symptomatology (Müller, et. al., 2014). In addition, Müller et. al., (2014) found that multiple exposures increased the risk for both clinical and subclinical PTSD.

Models of Trauma

A brief overview of several prominent theories will be provided below. The discussions have taken a developmental order, beginning with earlier theories, and linked the ideas to lead to the current theory underlying this study.

Stress Response and information processing theories. Early models of trauma such as Horowitz (1983) suggested that when faced with a life-threatening event, initial reactions are based on physiological responses, such as fight or flight, coupled with extreme emotional intensity. The processing of events is considered related to primary (immediate) and secondary (delayed) emotions (Brewin, Andrews & Rose, 2000). Information processing is considered the result of both conscious and unconscious interpretation of events and memories which relate to pre-existing schemas (Horowitz, 1976, as cited in Horowitz, 2011). Horowitz (1983) proposed, however, that individuals may deny the seriousness of a traumatic event or suppress their intense fears and emotions which can result in numbness of emotion, withdrawal and fantasising to avoid reality.

Attempts to assimilate the information from the trauma with existing schemas can create affective information overload and therefore defence mechanisms such as a denial phase may be employed, or extended as an attempt to protect them from continued threat (Brewin, & Holmes, 2003). However this ignores the need for the human brain to merge old and new information in order to assimilate this, and can lead to unprocessed information intruding into consciousness (Brewin & Holmes, 2003).

What may be considered ‘healthy’ in the trauma processing stage is an individuals’ ability to work through their experience and adapt and modify existing schemas in line with the new information or new reality (Brewin & Holmes, 2003; Horowitz, 1983). However, extended periods of being ‘stuck’ with the initial threat response on primary appraisals and emotions, coupled with continued intrusions and avoidance symptoms leads to the pathology associated with PTSD (Horowitz, 1983). This therefore takes the view that fully processing and assimilating information relating to the trauma is not completed or is blocked.

Horwitz’s model offers a useful account of how traumatic event-related information may not be sufficiently processed to support healthy functioning, and this is likely to impact on recovery (Cahill & Foa, 2004, cited in Friedman, Keane & Resick, 2007). These ideas alone do not fully explain whether individuals will maintain traumatic stress symptoms (Kessler, et. al., 1995). It offers limited suggestions as to the environmental factors influencing traumatic stress development and maintenance (Brewin & Holmes, 2003).

Information processing theories share some assumptions with the stress response model in that processing of traumatic events and their memories needs to be done effectively in order to avoid maladaptive or pathological consequences, but with a focus on the event itself (Creamer, Burgess, & Pattison, 1992; Foa, Steketee, & Rothbaum, 1989). In particular, Foa et al. (1989) described traumatic events as significantly violating an individuals’ sense of safety which lead to environmental cues tapping into and activating a fear network. This offered greater understanding of how the violation of assumptions can trigger and increase trauma reminders; however it remains limited to the understanding of fear rather than other emotions we now know to be associated with traumatic stress.

Emotional processing theory. This expanded on the earlier work of Foa et al. (1989) by considering individuals’ pre-trauma perceptions of the world and how these may be challenged, or confirmed by experience of a traumatic

event (Foa & Rothbaum, 1998; Dalgleish, 2004). Early recognition of negative appraisals of responses to trauma was considered with the emotional processing theory and acknowledged the potential role of self-criticism (in the form of negative schemas about self) as potentially maintaining PTSD symptoms (Foa et. al., 1989). Importantly, emotional processing theory had important implications for treatment for PTSD in the form of prolonged exposure (see section on treatment).

Cognitive Model of PTSD. Ehlers and Clark (2000) proposed what has become a prominent cognitive model in PTSD and psychology literature. They advocated that ineffective processing of traumatic experiences produces a current sense of threat, with an emphasis of fear as the primary affect involved in ongoing distress (Westbrook, Kennerley, & Kirk, 2011). However the model also allows acknowledgement of guilt and shame. The model describes the role of negative, or critical, appraisals, particularly of the self, in relation to one's behaviour or responses during a traumatic event. Peri-traumatic factors are also considered influential, such as dissociation (e.g. Murray, Ehlers, & Mayou, 2002) and emotional numbing. Ehlers and Clark's (2000) behavioural and cognitive strategies have also been empirically supported; avoidance of reminders of traumatic events, thought suppression and alcohol use (Ehlers and Clark, 2000; Brewin & Holmes, 2003) offering explanations as to why PTSD may be maintained.

Evolutionary Theories. Building from the earlier trauma models, Chemtob et al. (1988) contributed an evolutionary view on trauma responses proposing that the fear network (e.g. fight or flight) is constantly activated for those experiencing PTSD symptoms and sees individuals functioning in whichever survival mode was adaptive during their traumatic experience. This supports the notion of being stuck in an extended phase preventing the assimilation of emotional and physical information from the experience. However these theories do not specifically include behaviours such as 'freeze' (immobilisation).

Polyvagal theory. In addition to the ideas proposed by Chemtob et al. (1988) evolutionary perspectives have widened to consider our body's ability to regulate distress (Porges, 1995; 2007). From this standpoint, traumatic stress responses are a normal evolutionary response to threat, but the positive or negative consequences may be dependent on many factors for each individual (Christopher, 2004). Porges (1995) describes an evolved Autonomic Nervous System (ANS) which influences our interactions with the environment.

Cues such as emotional experience, facial expressions from others, and vocal communication inform this neural process which in turn supports regulation of our heart through activating the social engagement system (Porges, 2003). Such use of cues supports or hinders the regulation of the heart when under threat by evaluating risk in the environment (Porges, 2007). The notion of neuroception offers some explanation as to what is often referred to as 'gut instinct'. The process is unconscious and may not fit with our cognitive appraisal of the environment (Porges, 2004).

The fight or flight system is our more primitive neurobiological defence system. This is employed when neuroception deems the social engagement system as a less adaptive response for survival in a given situation (i.e. the environment is interpreted as threatening). More primitive again is the defence mechanism of 'freeze' or immobilisation. Considered the most primal strategy, it is often unhelpful (e.g. fainting) and therefore is utilised as a last resort (Porges, 2007). However its adaptive uses allow experience of pain to be reduced, as this is our body's method of dissociation. Freeze is considered a stress response which promotes a physiological state defined by drops in blood pressure and heart rate and essentially a 'shutting down' (Porges, 2004).

Overuse of the fight/flight or freeze systems however can cause other health and mental health difficulties. Whilst in fight/flight mode, the sympathetic nervous system responds with increased cardiovascular activity and immune systems are inhibited (Dennis, et. al., 2016). Increased time in such states been found to be associated with, and in some cased, predictive of, increased

inflammation (Dennis, et. al., 2016; O'Donovan, Neylan, Metzler, & Cohen, 2012) and increased cardiovascular risk (Hayano, et. al., 1990). Active fight/flight strategies also cause strain on mental health with associated higher levels of anxiety (Friedman & Thayer, 1998). It has also been found that when a group of people with borderline personality were faced with affective stimuli they demonstrated lower vagal activity (Austin, Riniolo, & Porges, 2007). It is a 'high alert' strategy and this can be considered in line with the hyperarousal symptoms of PTSD as reflective of higher sympathetic activity (Murburg, et. al., 1997) although it has been found that this is in response to trauma stimuli rather than notable differences in baseline sympathetic activity (Murburg, et. al., 1995). It is considered that extended periods of adopting our more primitive defence mechanisms can inhibit our ability to develop an effective social engagement system (Porges, 2007). As such, individuals will be less able to employ this more sophisticated way of regulating the body in everyday situations which may not include any active threat.

The vagal 'brake'. As discussed, the polyvagal theory proposes that the ANS regulates the body through a mylienated vagus nerve. This myelinated vagus is unique to mammals and it serves the function of a vagal 'brake' (Porges et al., 1996). This metaphorical 'brake' is able to rapidly inhibit or disinhibit the vagal tone to the heart and thus result in mobilisation or calming of the physiological state of an individual. The higher or lower the vagal tone, the faster or slower (respectively) the heart rate is, and this regulation by the vagal brake provides a neural mechanism which supports the body's need for mobilisation and social engagement behaviours (Porges, 2007). As such, dominance of the parasympathetic nervous system indicates ventral vagal dominance which promotes social engagement, whilst dominance of the sympathetic nervous system occurs when the vagal brake is released to allow for mobilisation defence mechanisms (Porges, 2011).

This vagal regulation of the heart is heavily involved in long-term consequences of stress (Porges, 2001; Sahar, Shalev, & Porges, 2001) and primary emotions experienced are related to these autonomic functions of the ANS (Porges,

1995). Evidence has been found to demonstrate higher cardiac vagal tone, or activity, to be associated with greater tendency to utilise distress management strategies (Geisler, Kubiak, Siewert, & Weber, 2013), such as seeking social support and engaging in attempts to change a stressor, or engaging in positive self-talk. This adds to previous literature demonstrating positive relationships between vagal tone and perceptions of social support (Schwerdtfeger & Schlagert, 2011), highlighting more active social engagement to manage distress.

Polyvagal application to traumatic stress. It has been found that vagal 'dysfunction' may be associated with an increased susceptibility to developing PTSD following traumatic road traffic accidents (Shaikh, et al., 2012). However research investigating the links between high or low baseline resting HRV in trauma survivors has been somewhat inconclusive, in part impacted by small sample sizes and the issue of co-morbidity (Chang, et al., 2013). Specifically, lower HRV (including high frequency HRV) has been associated with trauma (Lee & Theus, 2012). This has also been found when accounting for the presence of traumatic brain injuries in military populations (Minassian, et. al., 2015). Given the limited and thus far inconclusive evidence, heart rates and the influence of vagal regulation in those experiencing traumatic stress is an area worth further investigation.

Other Factors Influencing Traumatic Stress

Below, further discussion is offered in relation to factors potentially associated with the development of traumatic stress, and expanded discussion focused on the factors which may mediate or moderate the maintenance of trauma symptoms.

Mediating factors: primary responses to trauma.

(HRV). Respiratory Sinus Arrhythmia (RSA) (Porges, 2011), reflecting the increase and decrease in heart rate during breathing, provides information about the efficiency of the vagal 'brake' and related activation of the social engagement system, (Porges, 2011). RSA is a time domain measure of HRV

(Chang, et. al., 2013).Measurement of HRV relates to the ventral branch of the vague nerve, which controls parts of the body employed when interacting with others (facial muscles and heart). The term ‘social engagement system’ refers to its function in interpersonal interactions. The social engagement system is regulated through a strand of a mylienated vagus nerve and this allows us to subconsciously interpret our environment as safe or threatening.

Assessment of HRV has been used to measure the physiological alteration in a number of psychiatric illnesses including the effects of trauma-related cues in PTSD (Cohen et al., 2000). The limited research specifically investigating HRV and traumatic stress suggests less vagal regulation of the heart in these individuals, implying potential impairments in neuroception (Chang et al. 2013; Guédon-Moreau et al. 2012; Porges 2001). Baseline HRV may also be lower in trauma-exposed individuals than controls, although there are concerns around the methodological and sample issues (including heterogeneity in trauma populations studied) within the research (Porges, 2007). In addition, HRV has been found to be lower in those with PTSD during exposure to affective stimuli, implying lower parasympathetic activity and rigid response regulation (Lee & Theus, 2012; Hauschildt, Moritz, Jelinek & Peters, 2011; Tan, Dao, Farmer, Sutherland, & Gevirtz, 2011; van der Kolk, 2006).

In essence, high vagal tone is considered as a marker for “flexibility” in various physiological and psychological conditions (such as during traumatic experiences) and this is associated with higher HRV (Stein, Bosner, Kleiger, & Conger, 1994). Conversely, reductions in the responses of vagal autonomic function to physiological stimuli are associated with a lack of adaptive variability in behavioural and cognitive functioning, and with poor health outcomes (Friedman & Thayer, 1998). Measures of this ventral vagal activity offer a reflection of resilience, gauging how social support or psychotherapy can alleviate stress (Baldwin, 2013).

In relation to HRV and its potential to mediate the initial response and development of problematic trauma symptoms, the evidence is unclear

(Minassian, et. al., 2015). However, some findings, specific to diagnostic PTSD found that low HRV immediately following experience of a traumatic event was predictive of PTSD development (Shaikh, et. al., 2012). Minassian and colleagues (2015) explored HRV prior to trauma for a group of Marines, proposing that low HRV was a risk factor for developing PTSD. They found a modest association between active combat exposure and subsequent PTSD development, specifically in relation to a predominance of sympathetic activity (Minassian et. al., 2015).

Self-criticism. Considered an extremely pervasive feature of psychopathology (Gilbert & Irons, 2004) self-criticism is viewed as trait-like in psychopathology (Hartlage, Arduino & Alloy, 1998; Zuroff, Blatt, Sanislow, Bondi & Pilkonis, 1999) and can often be underlined by shame (Gilbert & Proctor, 2006). It has also been found to correlate highly with risk of depression (Murphy, et al., 2002).

The concept of self-criticism can be related to Horowitz's (1983) model, developing as a result of internal schemas based on internalised memories of critical others (Baldwin, 1992). Research supports this idea, finding that individuals who experienced critical home environments as a child are more likely struggle with experiencing positive emotions, particularly about themselves, as adults and is linked to increased psychopathology (Gilbert & Miles, 2000; Whelton & Greenberg, 2005). Self-criticism can result in an increased sense of threat and feelings of shame (Harman & Lee, 2010) which may subsequently influence appraisals of the trauma. As such, it may therefore be a mediating factor in relation to the initial response to trauma and influence the outcomes of PTSD development.

Links between self-criticism, shame and PTSD. Self-criticism is viewed as a key component of 'internal shame' (Gilbert & Proctor, 2006) and is the lens through which an individual evaluates themselves. It encompasses an individuals' internal experience of the self as hostile and critical (Gilbert & Proctor, 2006). Shame is considered problematic in preventing openness to

new challenges and the ability to experience positive emotion and is significantly associated with self-criticism (Gilbert & Miles, 2000; Whelton & Greenberg, 2005). Self-criticism is thought to develop through a variety of experiences including early trauma (Gilbert & Proctor, 2006). Having especially critical parents or peers can mirror qualities of trauma memories (Lee, 2005) and such humiliation or shaming experiences can result in a child developing in inner critic as they develop into adulthood, carrying fears of humiliation reoccurring.

Mediating and moderating factors: trauma maintenance.

Social safeness. It has been found that people who have difficulty with experiencing positive affect, including feeling safe, during times of high stress may then find it difficult to regulate negative emotions (Richter, Gilbert, & McEwan, 2009). Those who have limited emotional memories that are reflective of feeling safe are likely to be more self-critical in times of heightened stress (Baldwin & Dandeau, 2005). This sense of social safeness can be considered in the context of how people feel about or experience the behaviour of others towards them, and how this can feel supportive or critical to the individual (Gilbert, Cheung, Grandfield, Campey, & Irons, 2003).

Experiencing a sense of social safeness is considered to be prompted by cues of attachment from caregivers, friends, partners, as well as strangers (Liotti & Gilbert, 2011). When individuals feel socially safe it can reduce their sensitivity to threats and promote soothing (Cozolino, 2014; Panskepp, 1998) and social safeness has been demonstrated to negatively correlate with depression and anxiety (Gilbert, et al., 2011).

It is important to clarify that social safeness is different to the frequently researched PTSD risk factor of perceived social support (Kelly, Zuroff, Leybman, & Gilbert, 2012). Social safeness is viewed as more affective than cognitive in relation to the perception of social support (Pierce, et. al., 1991) and involves the experience of connectedness to others. Social safeness is considered distinct from social support, predictive of psychosocial suffering

(particularly avoidant and paranoid traits) and associated with high trait self-criticism (Kelly, et. al., 2012).

Current research into social safeness and trauma has focused on diagnostic PTSD rather than offering specific insights into subclinical traumatic stress, leaving a gap for further exploration.

Self-compassion. Compassion can be considered as kindness and an awareness of suffering with the desire to relieve it (Gilbert, 2009). It includes the motivation to acknowledge and recognise distress rather than deny it, and competency in tolerating such distress (Gilbert & Proctor, 2006). This involves skills in empathy to understand distress and meet this with warmth. The concept of self-compassion includes the use of these skills and motivations to relate to oneself, tolerating our own distress and being accepting of this rather than self-critical (Gilbert & Proctor, 2006). In addition, Neff (2003a) defines three aspects of self-compassion; self-kindness, common humanity and mindfulness, each having a negative counterpart; self-judgement, isolation and over-identification, respectively. Adopting this perspective encourages a person to view their mistakes and imperfections as part of shared human experiences, rather than self-criticising personal flaws (Neff, Kirkpatrick, & Rude, 2007).

Low self-compassion is associated with self-criticism, depression and anxiety and self-compassion is negatively associated with thought suppression and avoidance (Gilbert, 2009; Mills Gilbert, Bellew, McEwan & Gale, 2007; Neff, Rude & Kirkpatrick, 2007). However correlational studies do not offer insights into underlying mechanism or proposed causality. More recently, Cooper (2011) found that self-compassion moderated PTSD symptoms in a sample of 62 participants accessing services for trauma related distress. This was in cases where self-criticism was also low (Cooper, 2011). Previous research suggested that feelings of warmth such as compassion can often feel frightening for highly self-critical individuals (Gilbert, 2009; Lee, 2005).

Thompson & Waltz (2008) considered the literature connecting self-compassion and trauma symptoms. This built on the research demonstrating self-criticism, depression, and thought suppression as associated with trauma (Cox, MacPherson, Enns, & McWilliams, 2004; Rosenthal, Cheavens, Lynch, & Follette, 2006) and the negative associations between self-compassion and these factors (Neff, 2003b). In their study with a non-clinical sample, they found that the avoidance subscale of the Posttraumatic Stress Diagnostic Scale (PDS; Foa, Cashman, Jaycos, & Perry, 1997) significantly correlated with overall self-compassion, as measured by the SCS (Neff, 2003b). They proposed that due to self-compassion being linked to a willingness to engage with distress (Leary, Tate, Adams, Batts Allen, & Hancock, 2007), those with higher self-compassion would be less threatened by painful thoughts following a traumatic experience (or by trauma-related cues) and therefore engage in less avoidance behaviours (Thompson & Waltz, 2008). However, they acknowledged that the study could not identify whether lower self-compassion was a vulnerability factor for PTSD, or whether experience of trauma negatively impacts self-compassion.

Fear of compassion. Factors such as depression, anxiety and self-criticism can impede a person's ability to develop self-compassion, (Gilbert, 2009; McEwan & Gilbert, 2016; Mills, et al., 2007; Neff, et al., 2007) and some individuals may also develop a fear of compassion, (Gilbert, McEwan, Matos, & Rivis, 2011; Rockliff, Gilbert, McEwan, Lightman & Glover, 2008). It is acknowledged that for those who are highly self-critical or have high shame, experiencing warmth and compassion can feel alien and can trigger feelings of sadness and grief (Gilbert, et al., 2006; Rockliff et. al., 2008) which can feel overwhelming.

Fear of compassion towards self, towards others, and *from* others can cause resistance and doubt (Gilbert et al. 2011). Gilbert & Proctor (2006) explored the concept with a sample of chronic mental health patients and observed that when trying to engage with self-compassions, they experienced doubt, fear and resistance. However, it is proposed that repeated practice may enable people to overcome initial difficulties with compassion (Kelly et al. 2012). Gilbert (2010)

suggests this may be a result of desensitisation to the fears of compassion, acknowledging the potential overlaps in trauma therapies and evidence for exposure-based therapy (Powers, Halpern, Ferenschak, Gillihan & Foa, 2010; Wald & Taylor, 2007). Indeed, CFT follows aspects of a behavioural approach, viewing internal thoughts as able to act similarly to external stimuli (Gilbert, 2009).

By focusing on developing the ability to self-soothe and self-nurture, particularly for those who experience high shame and self-criticism (Gilbert, 2005), CFT can acknowledge and address such fears of compassion (see section 'Compassion Focused Therapy').

Treatment of PTSD

Little is known about the treatment seeking behaviours or effective treatment options for those with subclinical PTSD (Kornfield, Klaus, McKay, Helstrom, & Oslin, 2012). However, there is some evidence to suggest similar numbers of individuals seeking support, whether labelled subclinical or not (Bergman, Kline, Feeny, & Zoellner, 2015). In a random community sample of individuals with full and subclinical PTSD there was a similar rate of help-seeking for trauma symptoms between individuals with full PTSD (60.0%) and subclinical PTSD (52.6%) (Stein et. al., 1997). Research has indicated that negative social support from partners may predict poorer response to treatment (Tarrier, Sommerfield, & Pilgrim, 1999). This is specific to diagnosed PTSD, but may be important for subclinical PTSD groups also when considering barriers to treatment.

For those with diagnosed PTSD a number of treatments have been shown to be effective. Current evidence-based guidelines for treating PTSD (NICE, 2005) recommend Cognitive Behaviour Therapy (CBT) focusing on exposure to trauma memories and the negative reinforcement of avoidance behaviours (Cahill, Rothbaum, Resick & Follette, 2009) or Eye Movement De-sensitisation and Reprocessing (EMDR; Shapiro, 1989) which attempts to facilitate exposure to memories and subsequent memory processing through bilateral stimulation

(see Schubert & Lee, 2009 for a review). However consideration of the mediating and moderating factors for traumatic stress may offer insights into additional/alternative treatment aims focussing on reducing trauma symptoms and encouraging posttraumatic growth.

Though there is a lack of clarity in relation to therapeutic options for individuals with subclinical PTSD, recent research has begun to look at the treatment implications of targeting this population and there are some positive findings. Investigation of treatment response of subclinical PTSD participants to evidence-based Cognitive Processing Therapy (CPT; Resick, Monson, & Chard, 2007) demonstrated that both groups of veterans with subclinical and clinical PTSD had similar improvements in response to the treatment, in the form of reduced PTSD symptoms (Dickstein, Walter, Schumm, & Chard, 2013). Korte, Allan, Gros & Acierno (2016) proposed that actually sub-clinical symptomatic traumatised individuals may respond to psychological treatment quicker, or more effectively, than those will with full PTSD. They argued that this may be due to having fewer and less intense symptoms than clinical samples of PTSD sufferers (Korte, et al., 2016).

To examine this further they offered a Behavioural Activation and Therapeutic Exposure (BA-TE; Gros & Blake Haren, 2011) to combat veterans with either clinical or subclinical PTSD. They demonstrated that in their sample, subclinical PTSD veterans showed a slightly greater rate of change during treatment than the PTSD group, suggesting that the treatment response trajectory may be more promising for those with lower level trauma symptomology (Korte, et. al, 2016). This added to research conducted previously by Shiner, et. al., (2012) who investigated the stability of subclinical versus clinical PTSD over time, and following treatment interventions. They also demonstrated that for patients accessing a Veteran's Affairs mental health clinic, individuals with subclinical PTSD improved more quickly than those with full PTSD.

Bergman, et. al., (2015) explored treatment choices in a large community sample of trauma-exposed individuals, 16.7% of whom were considered to

meet subclinical PTSD, 76.5% of this subsample indicated experiences of impairment and of the overall sample, treatment preferences indicated that individuals preferred a combination of medication and therapeutic interventions. However it should be noted that the treatment modality was limited to the choice of prolonged exposure.

Based on their findings, Korte et. al., (2016) suggested that this may provide implications for subclinical PTSD populations' need for fewer treatment sessions. Indeed, there is some earlier evidence in PTSD literature that less severe presentations may require fewer therapeutic sessions (Van Minnen, Arntz, & Keijsers, 2002). In addition, research into other pathologies, for example anxiety, has found efficacy in treating less severe symptoms with brief interventions (Aune & Stiles, 2009; Veer-Tazelaar, et. al., 2010). As such, there is merit in exploring the efficacy of brief interventions for groups of individuals who may not meet the full requirements for a diagnosis of PTSD. Given that healthcare systems aim to offer cost-effective interventions for those in distress, excluding people because they do not meet a diagnostic threshold could exclude those who are at risk of maintaining trauma symptoms and impairments (Cukor, et. al., 2010). In addition, treating those with subclinical PTSD symptoms, may reduce costs if fewer sessions are needed, and prevent additional people going on to develop clinical levels of PTSD (Mylle & Maes, 2004).

Despite some positive preliminary findings in relation to treatments for subclinical PTSD, it is too in its infancy to draw conclusions. In addition, studies so far have only looked at few specific treatment options (i.e. exposure and behavioural approaches, Cognitive Behaviour Therapy; CBT). Covert, Tangney, Maddux, & Heleno. (2003) found that CBT was less effective for individuals who experienced high levels of shame and self-criticism, although some effectiveness has been cited in RCT of trauma-focused CBT for PTSD populations (Kornør, et al., 2008). However, it has been suggested that relatively few clinicians use exposure techniques in therapy despite the empirical support for this approach (Cook, Schnurr, & Foa, 2004).

When considering treatment orientation and theoretical models, there is some indication that both specifically trauma-focused and non-trauma-focused interventions are effective in the treatment of symptoms of trauma (Classen, et. al., 2011; Neuner, et. al., 2008). This is helpful to consider in the context of literature which reports higher attrition rates for trauma focused versus non trauma focused work (Imel, Laska, Jacupak, & Simpson, 2013). Finally, research also indicated that trauma focused therapy with a non-trauma adjunctive intervention, was found to predict better outcomes than the trauma focused intervention alone (Fueh, Turner, Beidel, Mirabella, & Jones, 1996). This literature is in the context of clinical PTSD; however exploration of similar concepts with subclinical PTSD is warranted.

Despite evidence that exposure therapy is effective in treating PTSD, it remains a difficult psychopathological concept to treat, and treatment failure for this population persists (Cukor, Spitalnick, Difede, Rizzo, & Rothbaum, 2009). In addition, given that shame and self-criticism are strongly associated with traumatic stress, and these difficulties may complicate positive responses to treatment interventions (Covert, et. al., 2013) it is pertinent that alternative psychotherapeutic approaches for subclinical PTSD are explored further.

Compassion Focused Therapy (CFT). CFT (Gilbert, 2005) has been used to explain some of the processes in trauma more recently (Lee & James, 2012). CFT adopts a three-system model (see figure. 4) which can be applied to traumatic stress. The model, developed out of social, developmental and evolutionary theory with a consideration of neurophysiology addresses how we regulate emotions and how this influences our state of mind. One focus of the CFT literature relates to the development of relationships with others, through external feedback from others (positive or negative) and our own internal processing of this information (Gilbert & Proctor, 2006). Gilbert (2009) describes CFT as building on observations that people who experience high levels of shame and self-criticism struggle with being compassionate towards themselves, and are particularly sensitive to threats in their external world.

The three-system model adopted by CFT considers a neurophysiological-informed understanding of emotion regulation (Gilbert, 2005; 2009). These are described below;

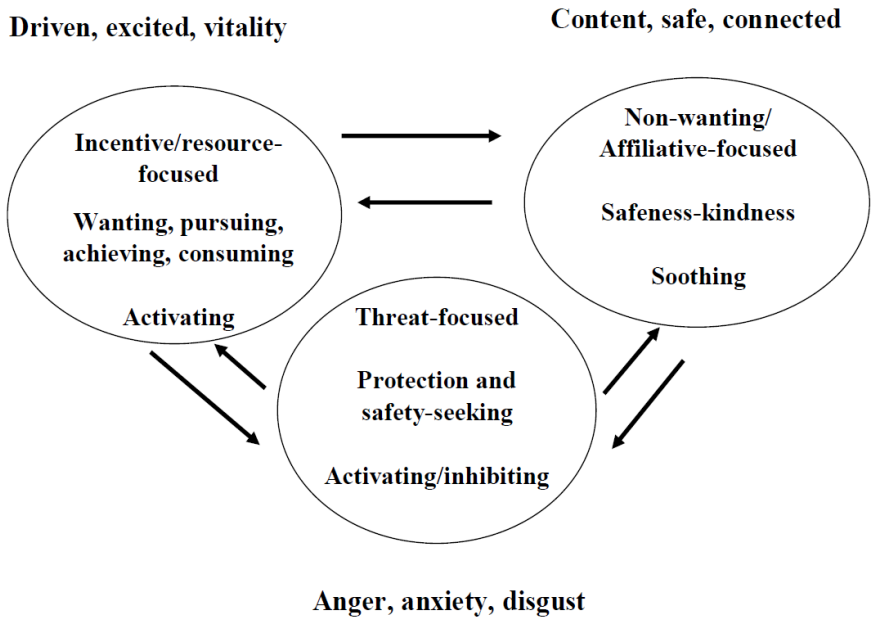

Figure 4. Three-systems model of CFT
(Reprinted from P. Gilbert (2009) The Compassionate Mind, with kind permission from Constable & Robinson Ltd).

Threat protection system: the function of this primal system is to detect threats and prompt feelings of anger, anxiety or disgust. This enables the body to become alert of the threat and prepares us for action in order to protect the self from harm. The prominent behavioural responses to this system being activated is the fight or flight response. Gilbert (2009) suggests this regulation system is easily conditioned and therefore early experiences are likely to play a key role in its development and sensitivity of this system to perceived threats. As such strategies in line with fight or flight might be relatively automatically or subconsciously engaged in when a sense of threat is presented. Self-compassion is considered a mechanism to deactivate the threat system, by increasing feelings of warmth and connectedness (see below; Gilbert, 2005).

Achieving and activating system (drive and excitement): the function of this system is to provide positive feelings which drive our desires and ambitions to achieve. Such experiences of pleasure aid the attainment of goals, whether achieving qualifications, making friendships or attracting a desired person and are linked to the feeling of arousal. It is viewed that this sense of pleasure is different to happiness due to its underlying dependence on reward or achievement.

Whilst both of these systems can influence our behaviours positively (readying the body for action in the face of threat, driving us to achieve pleasurable things), they can also lead to difficulty in instances when we may be driven to avoid negative experiences (Gilbert, 2009). It is suggested that for some, the drive system can become overactive in conjunction with a heightened threat system. CFT views this predominantly in relation to societal competition and status-seeking (Depue & Morrone-Strupinksy, 2005).

Affiliative and soothing system: this encompasses positive emotions, albeit differently to those experienced in the drive system. The affiliative (or contented) system is associated with feelings of social safeness, connectedness, and experiences of compassion for self and others. Gilbert (2009) describes contentment not just as the absence of threat but that there is a sense of safety created by caring behaviours from others. Drawing on attachment research, this is also viewed as an evolved system which is likely to have been shaped through early experiences of care and soothing (Gilbert, 2005; Mikulincer & Shaver, 2007). This can be considered in line with Porges' Polyvagal Theory (2007) with regards to the functions of the nervous system allowing soothing of the threat response in order to facilitate what CFT would call social engagement.

The soothing system acts as a regulator of the threat and drive systems, however these systems may become unbalanced for some individuals (Gilbert, 2009). As compassion stimulates feelings of safeness and connectedness, it

can provide a way of soothing the threat protection system (Kirsch, et al., 2005) and restore a balance in the three systems.

One of the difficulties presented by mental health systems having a focus on medical models, is that the idea of responses to trauma are frequently seen as adaptive (and therefore growth) or maladaptive (pathology) (Christopher, 2004). Research is then focused on investigating the impact of PTSD (Eagle & Kaminer, 2015). Again, much of this focuses on the pathological view of trauma. Posttraumatic growth, however is less well studied, particularly in the realm of sub-clinical PTSD. Posttraumatic growth (the ability to grow following adversity) is related to psychological well-being (Joseph et al. 2012) and accounts for positive change following traumatic events. Posttraumatic growth offers an additional outcome measure of progress in therapy (Joseph et al. 2012). Whilst individuals may be able to engage in therapy and challenge negative thoughts and appraisals of threat, they may remain self-critical (Rector, Bagby, Segal, Joffe & Levitt, 2000). CFT aims to increase the ability to generate feelings of contentment and warmth, reducing the perceived experience of threat and associated symptoms (Gilbert, 2005). This may link well with the concept of compassionate resilience which implies that the brain and body can then utilise compassionate skills (considered in the context of what we may call posttraumatic growth) and therefore help regulate the difficult emotions which may arise in the face of, for example, flashbacks (Gilbert, 2010).

As a third-wave model, CFT uses cognitive behavioural principles such as detailed assessments, formulations and treatment plans. Psycho-education focused on the three circles model and therapeutic interventions may include compassionate imagery exercises, mindfulness techniques and compassionate mind training (focusing on activating the affiliative, self-soothing system to reduce the dominance of the threat system). Therapy aims to de-shame individuals by helping them build an understanding of how their brain regulates their emotions and developing empathy for their own suffering (Gilbert, 2009). In addition, the recognition that some individuals can experience self-compassion as a potential source of threat and therefore be feared, is a key consideration

when therapeutically facilitating an individual to develop their affiliative system so that self-compassion become less threatening (Gilbert, et al., 2011). Figure 5 highlights how CFT interventions may fit with TAU for a trauma population. Interventions focused on strategies to reduce self-criticism and increase self-compassion may be an important facilitator of traditional therapies (Harman & Lee, 2010) by enabling individuals to develop an effective affiliative system and regulate the threat system. CFT has been shown to demonstrate improvements in psychological well-being more broadly (Neff & Germer, 2012). It is suggested that the work influenced by CFT can overlap with the trauma-specific therapies currently available (Gilbert, 2009).

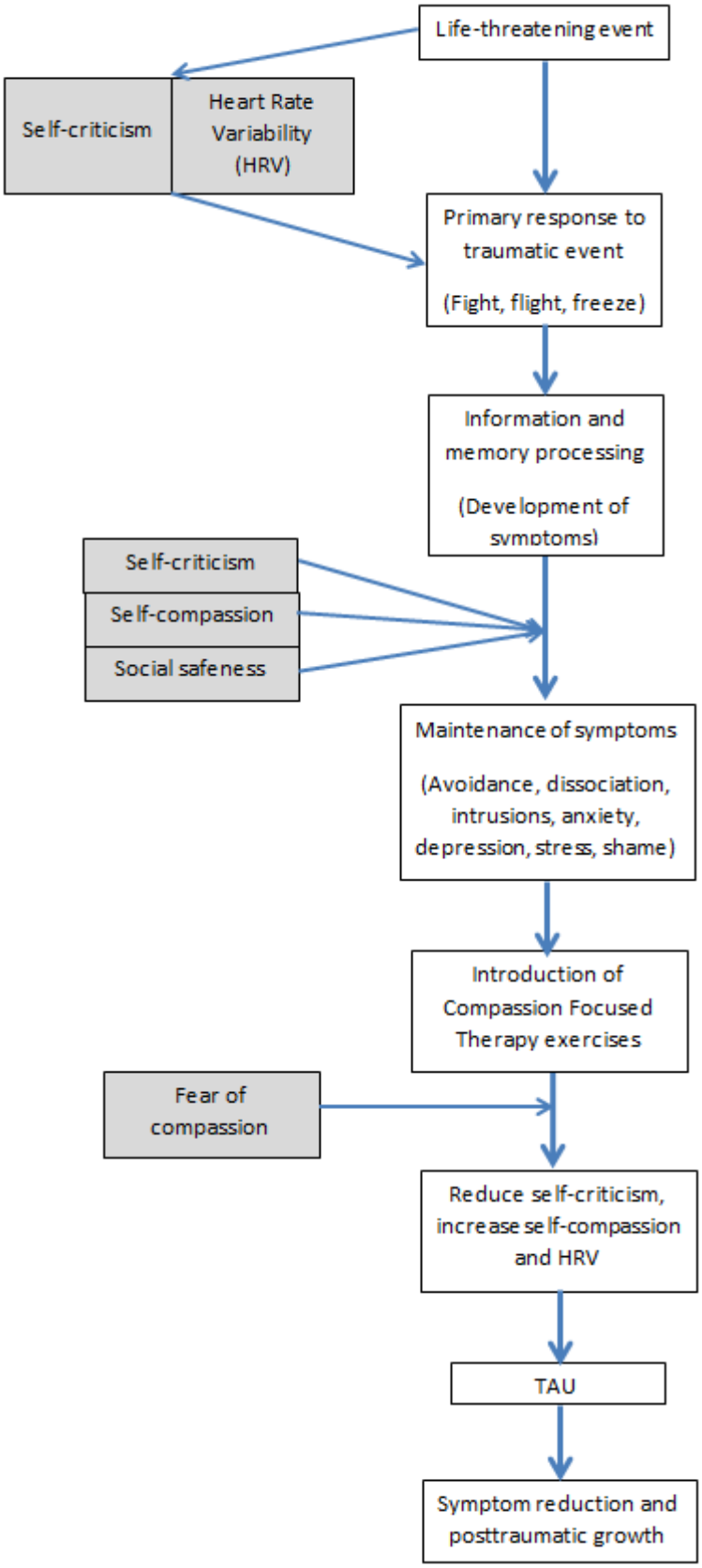

Figure 5. Overview of trauma and influential factors with addition of CFT.

Accessibility of treatment. One of the difficulties for those who experience traumatic stress is the ability to access therapeutic interventions. Whilst there is evidence for treatment approaches for PTSD, which one could argue may also apply to those with subclinical levels of traumatic stress (given the similar but less severe symptoms), people still do not always, or are not able to, access treatment early in their experiences of posttraumatic distress. The APMS study (McManus, et al., 2009) found that up to 70% of those with PTSD were not accessing or seeking treatment for their difficulties. In addition, many studies exploring military PTSD have discussed barriers to early interventions (e.g. Hoge, et. al., 2004; Shalev, Ankri, Peleg, Israeli-Shalev, & Freedman, 2011). As such, it is worth further investigation as to how service provision can be refined and more targeted for individuals not meeting diagnostic criteria, and yet suffer to a similar degree to those who do (Cukor, et. al., 2010).

As such, if and when individuals do seek and/or access treatment, it is likely to have been some time since their traumatic experience(s) (Shalev, et. al., 2011). Previous research suggests some evidence for the benefits of early intervention in treating traumatic stress (Foa, Keane, Friedman, & Cohen, 2009; Gelkopf & Berger, 2009). However it has also been suggested that delayed access to intervention does not increase the risk of chronic traumatic stress, and in fact suggests it remains useful to explore when early clinical interventions are unavailable or inaccessible (Gillespie, et. al., 2002; Shalev, et. al., 2011). However, it is worth noting that this view was provided in the context of traumatic events such as war and natural disaster when clinical intervention is pragmatically unavailable rather than it being due to individual not seeking help for other reasons.

There is also growing evidence to the effectiveness of phased-based approaches for trauma (Cloitre, et. al., 2011) which may include aspects of trauma-focused approaches and without trauma focused components (e.g. Dorrepaal, et. al., 2010; Steil, Dyer, Priebe, Kleindienst, & Bohus, 2011). These phase-based approaches have demonstrated trauma symptom improvements, although retain the limited ability for generalisation given different focuses on

trauma type subgroups (Cloitre, et. al., 2011). Nonetheless, the exploratory evidence may indicate preparatory intervention phases as an initial focus for traumatic stress.

Self-help interventions. Frequently used definitions for levels of self-help or self-practice interventions are provided by Newman Szkodny, Llera and Przeworksi, (2011). They differentiate between self-administered (SA: therapist contact only for assessment), predominantly self-help (PSA: therapist contact for instructions and guidance that doesn't exceed 90 minutes), minimal contact therapy (MC: more than 90 minutes of therapeutic assistance) and therapist administered (TA: regular contact with a therapist but with the use of self-help tools). Self-practice interventions are being increasingly investigated regarding therapeutic benefits and outcomes. However the range of treatment modalities is varied and therefore conclusive results of effectiveness are limited. The design of the current study adopted a SA approach, which has been referred to for consistency as self-practice.

Reviews for this format of self-help interventions have been published for pathologies including anxiety and depression and offer promising effect sizes when compared to waiting lists, and as a substitute for therapist involvement (Lewis, Pearce & Bisson, 2012; Talbot, 2012). However, there is little in the literature to offer conclusive evidence as to the benefits of self-help interventions specifically for traumatic stress. Research has considered specific intervention modalities for trauma with varying levels of guidance or therapist support, including writing exercises, modular computerised CBT interventions, internet and manual based cognitive and exposure interventions, with varying effect sizes (Possemato, Ouimette, & Knowlton, 2011; Ivarsson, et. al., 2014; Stockton, Joseph & Hunt 2014; van Emmerik, Reijintjes & Kamphuis, 2013). As such systematic reviews of self-help interventions for trauma are limited due to the focus on intervention format (Kuester, Niemeyer, & Knaevelsrud, 2016) or specifically targeting co-morbid issues, for example substance misuse (Roberts, Roberts, Jones, & Bisson, 2015).

Specifically considering self-help without therapist input, Ehlers, et. al. (2003) employed a RCT of cognitive therapy based self-help book, which did not demonstrate efficacy for acute PTSD. However there was no therapist contact at all, or any follow-up appointments which may have been a limitation.

McEwan & Gilbert (2016) piloted the use of a self-practice CFT intervention with university staff and students. They found that participants did not suffer any adverse effects of practising the exercises and noted significant increases in self-compassion and significant decreases in self-criticism, depression, anxiety and stress. They also demonstrated maintenance of these gains at six month follow-up with the exception of stress. They proposed that this may have been impacted by impending exams. The authors recommend further research with clinical populations, using controlled methods to explore outcomes (McEwan & Gilbert, 2016).

Recently, NICE (2005) have recommended that research needs to develop RCTs to explore the benefits of guided self-help interventions for mild-moderate PTSD symptoms. Initial responses to this recommendation include a piloted guided self-help programme for mild to moderate PTSD which demonstrated positive outcomes in terms of reduced PTSD symptom scores (using the Clinician-Administered PTSD Scale; CAPS; Blake, et. al., 1995) over an eight-week period (Lewis, Roberts, Vick, & Bisson, 2013). This study has informed a follow up RCT design although results are not yet available. However although the sample were considered to present with mild-moderate PTSD symptoms, they all had a diagnosis of PTSD, thus the gap for exploring traumatic stress (regardless of a diagnosis) remains.

Limitations of Existing Research

A recent review conducted by the King's Fund (McCrone, et. al., 2008) considered the cost of mental health in relation to the government and taxpayers. It assessed the current need for mental health services and the associated costs of these services, considering the potential impact that specific interventions may have on such costs. However, this review was limited in that

it excluded trauma (specifically PTSD as this was a diagnostic-driven report). The main reason for this exclusion was the difficulties in establishing prevalence rates for trauma, although the authors recognised the likely increase in prevalence given its “links to migration” (McCrone, et. al.,2008, p7). It is also highlighted that there were no known data sources enabling cost estimates of treatments for PTSD. Despite the emphasis on the significance of trauma to public health and particularly in light of large scale terror attacks (Jordan, et. al., 2004) and wars in Afghanistan and Iraq (Hoge, et.al., 2004), the literature informing our understanding of effective interventions that can be readily available to trauma populations remains limited.

Prevalence rates of sub-clinical traumatic stress, and for PTSD are limited, often focus on specific traumatic events, and are unrepresentative of true figures due to the continued incidences of events which are experienced as traumatic (crimes, natural disasters, war, etc.). Despite this, it is clear that it is an increasing problem both locally and internationally.

Rationale and Aims

Given the evidence presented, it could be viewed that traumatic stress may develop through an overactive threat protection system and an under-developed soothing affiliative system (Gilbert, 2005; Lee & James, 2012). This may be mediated by ineffective ventral vagal and nervous system functions (Porges, 2007) and by high levels of self-criticism which impedes an individual’s ability to achieve a sense of safety and connectedness, thus perpetuating the sense of ongoing threat (Gilbert, 1997).

In addition to these factors, the sense of threat and the associated traumatic stress may be moderated by the perception and/or experience of social safeness and by the ability to experience self-compassion. Developing higher levels of these factors may lead to a reduction in self-criticism, and enable individuals to experience a reduction in symptoms of traumatic stress, namely depression, anxiety and stress.

Given concerns regarding accessibility of therapeutic intervention for traumatised populations, and the potential benefits of self-help interventions, it may be that engaging in self-practice CFT can offer a way of addressing these moderating factors in preparation for accessing trauma-specific interventions. This may be by way of enabling individuals to compassionately face their traumatic experiences in therapy, or build their ability to manage self-critical experiences in difficult times during therapy.

Due to the lack of research in self-practice compassionate interventions for traumatic stress, and the literature around sub-clinical PTSD potentially leading to clinical levels, a comprehensive understanding of how CFT interventions may feed into traditional therapies is required. The current study aimed to contribute an early step in this process with a wider view that findings may implicate further thought on the societal costs of traumatic distress. To do this, it aimed to first develop a CFT intervention which could be deemed acceptable for use by a clinical population, with the view to build on this by evaluating the impact of a brief self- practice CFT intervention for a trauma population. It was hoped that exploring the impact of the CFT intervention on trauma symptoms, as well as on factors which are associated with traumatic stress from the literature, would enable consideration as to CFT being an effective adjunct to therapy. This would potentially raise the profile of CFT for a trauma population and promote thoughts as to how this may be incorporated into services in preparation for trauma-focused interventions.

Study Design

Given that the intervention script piloted by McEwan and Gilbert (2016) had not yet been evaluated with a clinical sample, and considering the literature identified moderating and mediating variables, exploration of adaptations to the script was required. In order to do this most effectively, the study was implemented in two phases.

Phase one consisted of a feasibility study, testing acceptability of a brief self-practice CFT intervention. This included making initial amendments to the CFT

intervention script based on the literature and through consultation with service users. This was then implemented with a clinical group of participants alongside therapy, allowing for further revisions to be made before implementation in phase two. The feasibility phase enabled preliminary analyses on the primary outcome measure with a clinical sample of participants as well as obtaining feedback on the ease of use of the script and perceived utility. Post-feasibility adaptations were then made before beginning phase two of the project.

Phase two implemented the revised intervention script, along with additional measures to assess variables related to the project aims. Phase two was specifically targeted at a trauma population for participants on a waiting list for trauma-specific therapy. Part of these aims enable the CFT intervention to be later evaluated as a potential facilitator for formalised trauma therapy. This potential third phase is outside the remit of this doctoral thesis, although work for this is ongoing and is planned for a future journal paper.

Epistemological Position

The objectives of the project were to investigate the effects of a theory-based brief intervention, specifically CFT, for trauma clients as an adjunct to treatment as usual (i.e. trauma focused interventions). The research was conducted from a critical realist perspective (Bhaskar, 1975, as cited in Sayer, 1992), acknowledging that truth may exist but within a context (Sayer, 1992). For this research project, the context was comprised of the services involved in either of the two phases of the project, and the experiences of those accessing the services.

The project does not aim to establish absolute causation but acknowledges that relationships between variables identified in the literature may have an impact on treatment outcomes and contextual elements, such as individuals' traumatic experiences. As such, a critical realist perspective allows for an inclusive rather than reductionist approach to be adopted when exploring various theoretical accounts (Bhaskar & Danermark, 2006). By doing this, it allows for the various factors identified out of the current literature to be amalgamated into controlled

trial designs, without predetermining weight and influence of specific factors or mechanisms; this is empirically tested based on the outcomes of data analysis.

Data Storage

Questionnaires completed by participants in both phases were kept on an electronic database on a University-approved laptop. This was password protected and participant identifier codes were generated to label the data. As such, no personal information was held on the electronic database. All signed consent forms were handed in to the administration team at the University of Lincoln for secure storage.

Questionnaires were only given to participants once they had signed the consent and all questionnaire data was uploaded to a Microsoft Excel file on the password protected university laptop, using only the identifier codes. Paper copies of the questionnaires were also held for secure storage at the University of Lincoln.

Additional Ethical Information

An ethics application was submitted to the School of Psychology Research Ethics Committee (SOPREC) at the University of Lincoln, to the Research Ethics Committee and to the Research and Development departments for Nottinghamshire Healthcare NHS and Lincolnshire Partnership Foundation Trust. The study was also discussed with Paul Gilbert and has his support. Approval was granted from Wales REC 4 with the condition that all relevant NHS R&D sites approved the research. This was also obtained.

Safety and well-being.

It was important to consider the potential event that participants might find the intervention difficult or experience distress during their practice in the context of their current experiences of traumatic distress. Consideration of this also took into account the literature regarding fear of compassion (Rockliff, et. al., 2008). To address this possibility, specific acknowledgement as to the potential for fear of compassion and associated difficulty was included in the participant

information sheets and participants were encouraged to discuss any concerns they might have before taking part with the primary researcher. Participants were encouraged from the outset to discuss any concerns or distress with their identified clinicians if they needed additional emotional support. All local collaborators had also agreed to discuss any concerns about the project should participants raise this in therapeutic appointments with them.

In addition, all participants were asked to consent to their GPs being informed of their involvement of the research. This consisted of a covering letter being sent to the GP and a copy of the participant information sheet. All GP letters were sent by identified clinicians and their local administration staff in order to minimise access to personal information of participants by the researcher.

For the purpose of maintaining clarity of the overall thesis research, the remainder of this extended paper is split into sections related to phase one, followed by phase two. Below is a draft manuscript for the phase one study, which is then followed by extended method, results and discussion sections for phase one. Additional background literature has not been added to the manuscript here as it is covered in the ‘Extended Background’ section at the beginning of the thesis. Following this, extended sections for phase two will be discussed in additional detail to the journal paper.

Phase One
(Draft Manuscript)

Study Aims and Rationale

This study aimed to test the feasibility and acceptability of a self-practice CFT intervention script with a clinical population over a brief period to obtain feedback on its ease of use and any impact it may have on symptoms of depression, anxiety and stress. This aimed to further the findings of McEwan and Gilbert (2016) with a clinical population accessing mental health services.

The aims were threefold:

- To adapt an extant brief CFT intervention for a clinical population based on trauma literature;
- To establish acceptability and feasibility of the modified brief CFT intervention for a clinical population;
- To inform the second phase of a wider research project entailing a pilot-RCT with a trauma population.

Method

Ethical approval. The study was granted ethical approval by the host university and the NHS Research and Ethics Committee WALES/4. In addition, Research and Development Ethical approval was obtained from two local NHS Trusts (see appendix D for all correspondence relating to ethical approval and appendix E for the study protocol, and appendix F for approved recruitment materials).

CFT intervention. Kind permission was given by Professor Gilbert for the intervention script to be utilised and adapted for the current project. This original version of the CFT intervention included an explanation of compassion and why to choose this as a focus, as well as instructions for practising compassion. It included several exercises designed to increase self-compassion including breathing exercises and compassionate imagery exercises focused on self and others. The underlying premises of the exercises

remained throughout the development process with adaptations made to the presentation of information and level of detail.

The initial adaptation process included simplification of aspects of the script and reducing the overall word count to ensure it was more accessible as a brief self-practice. Consideration was given to the trauma literature, specifically taking into account the literature around increased experiences of self-criticism and fear of compassion (Gilbert, 2009; Rockliff, et al., 2008). Instructions therefore explicitly acknowledged the potential for the practice as difficult and ways to approach it if this was the case, such as returning to earlier exercises before moving onto the later ones if participants needed more practice. Professor Gilbert collaborated throughout the development process, offering agreement with amendments made. The underlying principles of the CFT intervention were maintained; building self-compassion and reducing self-criticism.

Following this initial adaptation, service users' ideas were sought through consultation with Service User and Carer's Advisory Panel (SUCAP) members. This was done prior to testing feasibility and acceptability of the intervention. As a result of these consultations, the intervention was amended to include explicit instructions for participants not to focus on traumatic events they had experienced. It was made clear that this would be addressed in any later trauma-specific therapy they may access. This was considered necessary given that the CFT intervention was likely to be novel to most participants and therefore practising something new immediately with a focus on traumatic events may be too difficult for some clients completing self-practice exercises without therapist support. This was particularly considered given the literature for subclinical PTSD populations and the potential increased likelihood of suicidality (Marshall, et al. 2001). In addition, the SUCAP members highlighted that having this made explicit would serve as a reminder to participants to maintain a focus away from the trauma for the self-practice. Participants were instead encouraged to focus on milder difficulties and stressors of their choice. In addition, SUCAP members suggested ensuring minimal use of acronyms in the script as it was reported by an ex-veteran member that these could at times

be similar to those used in the forces; therefore presenting as potential triggers for their traumatic experiences. Involving service users in the initial development of the project is something the SUCAP members have reported being a positive experience as it allowed their thoughts and collective experiences to be heard and considered in clinical interventions being developed and evaluated. This meant they could be involved in development of a study which then went before the ethics board. (See Appendix G for this version of the script).

Sampling and recruitment. Participant sampling for the feasibility and acceptability study was opportunistic, seeking voluntary engagement from clients currently accessing services, although services were chosen based on locality to the research base of Lincoln University. The sample size for this stage was not explicitly defined. However, it was taken into account what might be a reasonable way of determining when to end the feasibility phase. The decision was made that once there were no new ideas or suggestions being proposed to amend the intervention, and agreement appeared to be reached, the feasibility could be considered to be completed. Target sample sizes for pilot and feasibility studies inherently involve a level of uncertainty and preliminary targets can be often be inaccurate due to difficulties in predicting attrition rates with a novel intervention (Billingham, Whitehead, & Julious, 2013).

Participants were required to be able to understand verbal and written instructions in English to be able to engage in the research. This avoided difficulties associated with translating the intervention at this stage due to time and financial resources. As it was a new intervention, and was not validated or previously used with clinical populations, and some of the assessment measures were not validated in other languages.

The sample for this stage of the project was sought from the community forensic service in Lincolnshire and from the (SUCAP) affiliated with the Trent Doctorate in Clinical Psychology. Many clients accessing the community service, and those involved with SUCAP, have previous experience of traumatic events and symptoms of depression, anxiety and stress. In addition, these

sources of recruitment were considered appropriate given that all potential participants who were eligible would already have an actively involved therapist or clinician assigned to their care should they need additional support alongside their research involvement.

Procedure. Psychologists based at the community forensic service were provided with information about the research and information sheets with contact details to give to their clients. This had my contact details on but verbal consent was also sought by the clinicians for me to contact their clients to discuss the project further. This allowed contact to be made with those who might find taking the first initiative difficult. The same process was followed for SUCAP members and they were informed of the study by a University lecturer who supports in organising the SUCAP meetings. The research was given as an agenda item in a SUCAP committee meeting and members then contacted me via email to discuss the project further.

For those who were interested in taking part, the opportunity to ask questions was provided and aspects of the information sheet were clarified where required. Participants then signed the consent form and completed the primary outcome measure (Depression, Anxiety and Stress Scale: DASS-21; Lovibond & Lovibond, 1995). They were then given the CFT intervention script in written and audio (CD) format and asked to practice this over a two-week period on a daily basis. They were offered the opportunity to engage in the study alongside therapy they were already receiving. Clarification as to who they would contact if in need of additional support during their involvement was sought and all participants had an identified clinician who they could contact. Queries or support in understanding aspects of their research involvement or the intervention script were directed to me. Practical support could be offered by the primary researcher but therapeutic input was limited to their current clinicians. Participants were provided with a record sheet (Appendix H) to support them in writing down when they practiced, how long for, and any comments they had about it at the time. This then formed part of the feedback for stage one of the research. Participants were requested to provide qualitative feedback on the

ease of use, clarity of instructions, and perceived benefits of the intervention (Appendix I). Participants were asked to practice the intervention over a two-week period. The timescale was chosen as a result of the findings from the McEwan & Gilbert (2016) study which demonstrated good effects of the intervention over this time period with a non-clinical population

Participants were invited to a final appointment at the end of the two weeks where they were asked to complete the DASS-21 for comparison data to their pre-assessment measure and the feedback questionnaire mentioned above utilising Likert scales and a space for free text feedback if they wished to provide further comments. These results were then used to inform stage two of the research project with regards to amending the CFT intervention script and offering clinical data for power calculations and effect sizes.

All participants were able to keep the CD and written scripts following their involvement and were encouraged to continue practising if they so wished.

Participants. In total, 11 participants expressed an interest in phase one; three withdrew due to external events impacting on their ability to begin the project. Therefore eight participants completed the feasibility study. Participants were recruited through the primary researcher's contacts with adult forensic community services and the university SUCAP. They were not required to have experienced a traumatic event for purposes of the feasibility study, although participants may have done so. They were currently accessing mental health services or had contact with a mental health professional (Psychologists or Psychiatrists). Participants indicated that they were either part way through therapeutic interventions or were seeing clinicians only for follow up assessments. As such this was a sample of participants who were not only just beginning therapy sessions. Participants were recruited via their clinicians by providing information sheets. They were provided with contact details for the primary researcher and/or verbally consented to be contacted by the primary researcher.

Assessment. Participants were seen either at the NHS base where they saw their mental health clinician or at the local University. They were given the opportunity to ask questions following receipt of participant information sheets from their clinicians. It was clarified that practical support for the CFT intervention during their involvement could be provided but not therapeutic input. All participants were encouraged to speak with their associated clinicians if they required additional emotional or therapeutic support.

Participants completed the Depression, Anxiety, and Stress Scale: Short Form (DASS-21; Lovibond & Lovibond, 1995) following signing a consent form for their feasibility study involvement. The self-report instrument, designed to measure negative emotional states of depression, anxiety and stress, demonstrates good reliability, with findings from .82-.97 across the subscales (Osman et al. 2012) as well as sensitivity to change (Page, Hooke & Morrison, 2007).

Participants were then given the CFT intervention script and asked to practice this for a minimum of five minutes on a daily basis for the next two weeks. They were provided with a diary sheet to support their self-monitoring and to inform their feedback appointment at the end of the two weeks. Qualitative feedback questionnaires were also completed at the end of two weeks (see appendix I).

CFT Intervention. The updated CFT script (Appendix G) was provided in both written and audio format for participants so as to allow for preferences for audio versus written scripts to be followed. It comprised of a definition of compassion, its benefits and instructions for practising compassionate exercises. The compassion exercises were (i) soothing rhythm breathing; (ii) practising saying hello in neutral and friendly voice tones and facial expressions; (iii) compassion imagery; (iv) focusing compassion on others; (v) focusing compassion on self and; (vi) focusing compassion on challenges. Each exercise was followed by a suggested time to spend practising each one, with the exercises totalling five minutes. Participants could use either the audio or written versions. They could choose what time of day they practised and were

instructed that they could practice for longer than the required five minutes if they wished.

Results

A total of 11 participants demonstrated an interest in the research and completed the initial appointment. However, three withdrew from the study due to external events impacting on their ability to engage. Therefore a total of eight participants completed their involvement in the feasibility phase of the project (three men, five women). The mean age of the sample was 46.88 years (*SD* = 11.79 years). Three participants were from the community forensic team and five from SUCAP.

Statistical analysis. All participants completed the DASS-21 (Lovibond & Lovibond, 1995) pre and post CFT intervention. The data set was explored and no outliers were detected. Assumptions of normality were also met, as tested by Shapiro-Wilk test (all subscales ranging from $p = .111$ to $p = .532$). Participants scores of depression, anxiety, stress, and total scores significantly decreased following the two week period in which they practiced the intervention. Paired samples *t*-tests demonstrated a significant reduction across all subscales on the measure and across total DASS-21 scores from pre-post CFT over the two-week period (DASS-21 total scores: $t(7) = 3.97$, $p<0.01$). A large effect size was found ($d = 1.40$) on the DASS-21 total scores over the two week period demonstrating positive findings following intervention for a clinical population.

Qualitative feedback. Qualitative feedback was analysed using summative content analysis (Potter & Levine-Donnerstein, 1999; Mayring, 2014) as a method of quantifying qualitative information in a useable way to make subsequent changes to the intervention script. This method utilises counting frequencies of qualitative words or phrases to summarise the data [discussed in further detailed in the extended results].

Feedback indicated good acceptability of the CFT intervention with some proposals for small changes to be made to the script (see Appendix J for transcripts of feedback). The following amendments were made based on the feasibility and acceptability phase;

- Clearer instructions in the “saying hello to yourself” exercise to explicitly offer flexibility in how to practice this exercise
- Re-recording of the audio version to included silences for practising the exercises so participants do not have to pause while they practice.

Discussion

The current study consisted of a feasibility and acceptability study for a brief self-practice CFT intervention with a small clinical sample of community participants. This was a first step in expanding on a previous study exploring a previous version of the brief CFT intervention, with a non-clinical sample (McEwan & Gilbert, 2016). The acceptability was tested with a clinical sample and sought feedback on its ease of use and potential changes for improvement. In addition, effects of the intervention on depression, anxiety and stress were explored.

This study demonstrated significant large effects of the CFT intervention on symptoms of depression, anxiety and stress, demonstrating larger effects than the results found in the McEwan and Gilbert (2016) study. This offers potential clinical support for the benefits of a brief self-practice CFT intervention for a small clinical sample of clients accessing community mental health and community forensic services. In addition, positive feedback was given in relation to the ease of use of the script and its perceived helpfulness supporting the feasibility aspect of the intervention. Coupled with the low attrition rate presented in this study, it would suggest that the intervention was accessible to those who took part.

Limitations

As the study was testing feasibility and acceptability of the specific CFT intervention script, sampling was targeted to a local service where clients continued to receive treatment as usual. As such, there was no control group for this phase of the wider research project. Therefore we cannot compare the results of the sample to clients in a similar situation to those involved. Consent was not obtained from clients accessing the community services to complete the DASS-21 outcome measure whilst engaging in therapy, without accessing the CFT intervention.

Another related limitation is that information was not collected about participants' therapeutic treatment with their clinicians at the mental health services. Whilst this would be difficult to address given ethical considerations around client confidentiality in their treatment sessions and the fact that the research was conducted from an outside organisation (i.e. a researcher not working in the service they were engaged with), seeking consent to do so may have resulted in fewer volunteering participants. However, it does mean that we cannot ascertain from this study whether reductions on the DASS-21 were a direct result of the CFT intervention. Nonetheless, the qualitative feedback indicates that participants attributed some of their noted improvements to be related to practicing the intervention, with comments noting (e.g. "this is the only thing that's new") and the majority of the participants had been attending therapy for a number of sessions or were only attending for follow-up appointments.

Future Research

Despite the limited levels of control imposed in this study, it has provided valuable and promising evidence to build on in a subsequent phase of a wider research project forming a pilot-RCT, which aims to develop the CFT intervention and evaluate this with a trauma population.

Findings from this phase are important and open up the possibility for the intervention to be explored further as a useful adjunct to psychological therapies

more broadly and to investigate this on a larger scale. The participants in this study were engaged in services and therefore were practising the CFT intervention alongside other more formal therapies.

Adopting a larger and more controlled study design would add to both the CFT and self-help literature in clinical settings. It would therefore be useful as a next stage in evaluating this more widely as an adjunct to other psychotherapeutic interventions, perhaps to those on waiting lists in mental health and community forensic services on a larger scale. This would allow for more in depth evaluation of the CFT intervention as an adjunctive rather than parallel intervention as it was in this study.

Phase One: Extended Method

Sample Size Calculations

Formal sample size calculations were not generated for phase one of the research project. Whilst justifications for target sample sizes are required for this type of study, formal power calculations are not (Billingham, Whitehead, & Julious, 2013). Billingham and colleagues (2013) audited registered UK feasibility and pilot studies and found that depending on the aims of the studies, sample sizes ranges from 8 to 300. In addition Stallard (2012) recommends calculating sample sizes being 0.03 times the sample size planned for the definitive study (this is generally in relation to pilot studies). As the initial target for phase two of the research project was up to 40 participants, the sample size of 8 for the feasibility and acceptability study was adequate for these guidelines.

Additional DASS-21 Information.

The DASS-21 was the primary outcome measure in the study given the association with depression, anxiety and stress with traumatic stress as key symptoms. This is a 21-item shortened version of the DASS-42, (Lovibond & Lovibond, 1995). It is a self-report instrument designed to measure negative emotional states of depression, anxiety and stress. Each subscale consists of seven items. The DASS-21 is considered to have advantages over the full version in that it is shorter and hence less burdensome on clients, and it has been demonstrated to have a cleaner latent structure that the longer version (Henry & Crawford, 2005). In addition, Henry and Crawford (2005) also found the DASS-21 to be comparable with other validated measures for depression and anxiety in particular (e.g. the Beck scales for anxiety and depression).

McEwan and Gilbert's (2016) study using the original CFT intervention script with a non-clinical sample reported significant decreases in each of the three subscales of the DASS-21 through analysis using MANOVA (depression; $F(1, 43) = 7.46$, $p = .009$, $\eta_p^2 = .148$; anxiety; $F(1, 43) = 8.93$, $p = .005$, $\eta_p^2 = .172$; stress; $F(1, 43) = 18.95$, $p = .000$, $\eta_p^2 = .306$.

Phase One Analysis

The outcome data for this phase was both quantitative and qualitative. Quantitative data was categorical and interval. To illustrate descriptives for the sample, means and standard deviations are used for interval data, with percentages and frequencies used for categorical data (e.g. gender and feedback regarding continued use of the intervention).

Feedback data included quantitative data in the form of interval data from Likert scales. In addition, brief qualitative data was collected and analysed using summative content analysis (Powers & Knapp, 2010).

Assumptions. The assumptions required to be met for a paired-samples *t*-test are for data to include one independent variable (in this case the DASS-21) with two categorical, related groups (in this instance, the group of eight participants who completed pre and post measures of the DASS-21).

Whilst the paired samples t-test is considered relatively robust to violations of normality, this was tested for validation. To test for normal distributions on the subscales, the Shapiro-Wilks test of normality was employed. Additional tests of normality included the assessment of skewness and kurtosis by converting these scores into z-scores. Conservative use of skewness and kurtosis scores are considered acceptable with an equivalent z-score within ±2.58 demonstrated normal distribution (Laerd Statistics, 2016), although Field (2009) recommends scores of ±1.96 (one standard deviation) should be employed as the limit which indicates scores being outside of a normal distribution.

Difference between variables. In order to test the difference in DASS-21 scores pre and post CFT intervention for the feasibility study, the means for each measurement point would need to be compared using an independent samples t-test. Separate tests were conducted for all pairs of subscales (pre and post measures) of the DASS-21 which met the assumptions outlined above.

Content analysis. Content analysis has been used historically as both a qualitative and quantitative research method (Berelson, 1952). However since then it has often been used as a quantitative method to analyse qualitative data (Morgan, 1993). Primarily for analysis of the qualitative feedback from participants, summative manifest content analysis was employed (Potter & Levine-Donnerstein, 1999). The focus of analysis is on counting the frequency of specific words or phrases and comparing their frequencies to other words and phrases in the material (Mayring, 2014). The scope for this analysis was not on interpretation of underlying meanings of participants' suggestions for changing the interventions script, or to interpret their reported experiences of practice. As such, a purely quantitative analytical approach was taken.

Phase One Extended Results

Missing data. There was no missing data and therefore no procedures for missing data needed to be followed.

Outliers. Boxplots were explored to detect any outliers in the data set. There were no outliers present in the data set for phase one.

Tests of normality. Normality was assessed for the requirements of parametric testing of the DASS-21 results. This was tested for using the Shapiro-Wilk test of normality, recommended for small samples (Laerd Statistics, 2016). A non-significant test result indicates that a data set is not significantly different from a normal distribution. Analysis of each subscale and total DASS-21 scores indicated that data were normally distributed for this sample.

Standardised z-scores for skewness and kurtosis were calculated for each of the subscales and DASS-21 total scores. All z-scores fell within the Field (2009) recommendation of ±1.96 from the mean.

From these tests, it was concluded that the DASS-21 met the assumptions required to implement a paired-samples t-test.

DASS-21 outcomes. The DASS-21 was completed by all participants at both pre- and post- CFT practice. This enabled a brief measurement for comparing changes in levels of depression, anxiety and stress during their involvement with the study. Effects of the original CFT intervention were found in a non-clinical sample over a two-week period (McEwan & Gilbert, 2016) and therefore it was anticipated that findings of a similar magnitude and direction may be found here.

Paired samples *t*-tests were used to determine whether there was a statistically significant mean difference between each of the DASS-21 subscales and the DASS-21 total scores for participants following completion of a two-week period of practising the CFT intervention. See table 9 for means and standard deviations.

Table 9; Descriptive data for the DASS-21 subscales.

Subscale/Scale	**Pre**		**Post**	
	M	*(SD)*	*M*	*(SD)*
Depression	9.88	(2.28)	7.63	(2.14)
Anxiety	8.00	(1.76)	5.63	(1.67)
Stress	11.75	(1.45)	8.38	(1.95)
Total	29.63	(4.99)	21.63	(5.52)

Paired samples *t*-tests for each of the subscales were $t(7) = 2.91$, $p = 0.023$ (depression), $t(7) = 2.52$, $p = 0.040$ (anxiety), and $t(7) = 2.53$, $p = 0.039$ (stress).

In addition, the test-retest reliability for the DASS-21 for this sample was calculated, demonstrating good reliability in phase one's clinical sample for all DASS-21 subscales and total scores ($r = .730$ to $.931$).

Feedback questionnaires.

Quantitative data. Responses to the quantitative Likert scales are discussed below. Data is reported in terms of frequency of responses to each question.

Question 1 – all participants reported finding the instructions ‘easy’ or ‘very easy’ to follow (62.5% rating instructions as ‘very easy’ and 37.5% rating them as ‘easy’).

Question 2 – 75% of participants rated the CFT intervention as ‘useful’ or ‘very useful’, with one participant rating the intervention is ‘a little’ useful and one participant rating it as ‘somewhat’ useful.

Question 3 – 62.5% of participants stated that they practiced the CFT intervention daily, one participant practised every other day, one participant practiced ‘occasionally’ and one participant practised just ‘once or twice’

Question 4 - the majority of participants reported that they would continue to use the exercises (n=7). One participant reported that they wouldn’t continue to practice the script as they felt their recovery was going well and that they did not feel the need to.

Qualitative data; content analysis. All eight participants offered some qualitative information on their feedback sheet, although not all offered recommendations for CFT intervention changes. Summative manifest content analysis (Potter & Levine-Donnerstein, 1999) was performed to summarise and use the qualitative information provided.

Feedback for amendments was provided by all participants and is highlighted in the amendments to CFT intervention section. Below, table 10. is the result of the content analysis indicating frequencies of words and phrases which related to change ideas, positive qualities and negative qualities of the intervention.

Where specific comments related to a specific exercise in the intervention, this was indicated.

Table 10. Summative content analysis.

Words/phrases	Content Type	Exercise	Frequency
Pauses built in	Change	All	2
Disrupted	Change	All	1
Choice	Change	2: saying hello	1
Set regular time	Change	All	1
More visual	Change	2: Saying hello	1
Good tempo	Positive	All	1
Well structured	Positive	All	1
Most profound	Positive	2: Saying hello	1
Recommend it	Positive	All	1
Helped/helpful	Positive	All	5

Leaving gaps in the CD to encourage practising of exercises was considered beneficial to enable participants to listen to it all the way through rather than having to pause the instructions; this had caused some to feel disrupted. There was some variation in the interpretation of exercise two “say hello to yourself”. Some participants had interpreted the requirement of using a mirror to watch themselves practice this, whilst others did not and reported struggling with doing this. Overall proposed changes were minimal and easily incorporated to the updated script. (Appendix K for tracked changes of the script).

Amendments to the CFT Intervention. The CFT intervention script as a result of the feasibility and acceptability phase is outlined below;

- Suggesting to participants that a set time each day was included in verbal instructions during the initial appointment session rather than a set instruction in the script. This was to enable choice as the feedback on this aspect varied from person to person;
- Clearer instructions in the second exercise “say hello to yourself”. These explicitly stated that people could choose whether to use a mirror if they felt comfortable or whether they wished to close their eyes and focus on the sensations of the practice;
- The audio version of the intervention was re-recorded to reflect all changes made in the written version and included the addition of timed sections of silence. They were preceded by instructions that silence would follow and that this was for the allotted time to practice the exercise.

Phase One: Extended Discussion

Phase one consisted of a feasibility and acceptability study for a brief self-practice CFT intervention with a small clinical sample of community participants. This was a first step in expanding on a previous study exploring an earlier version of the brief CFT intervention, with a non-clinical sample (McEwan & Gilbert, 2016). The acceptability was tested with a clinical sample and sought feedback on its ease of use and potential changes for improvement. In addition, effects of the intervention on depression, anxiety and stress were explored.

This study demonstrated significant large effects of the CFT intervention on symptoms of depression, anxiety and stress, demonstrating larger effects than the results found in the McEwan and Gilbert (2016) study. This offers potential clinical support for the benefits of a brief self-practice CFT intervention for a small clinical sample of clients accessing community mental health and community forensic services. In addition, positive feedback was given in relation to the ease of use of the script and its perceived helpfulness supporting the feasibility aspect of the intervention. Given the limited attrition rates presented in this study (only one person dropped out from the study), it would suggest that

the intervention was accessible to those who took part, with qualitative feedback supporting this.

The finding of large effect sizes on the DASS-21 following completion of a two-week practice of the CFT intervention provided some very promising preliminary results. It is acknowledged that these results are tentative and do not provide sufficient evidence to promote the widespread use of the intervention to all clinical populations. It provides initial evidence that for those accessing services, it may offer some additional benefits alongside formal psychotherapeutic interventions to aid reduction of experiences of depression, anxiety and stress. Indeed, the participants who engaged in the intervention were either already in therapy (and had been so for some time) or had completed formal therapy and were engaged in services for low level support or review appointments.

Whilst these results are on a small clinical sample, it calls for further studies to investigate the benefits of this as an adjunct to other therapies on a larger scale and adds to the promising literature regarding to the benefits of CFT.

Limitations

Given the study was testing feasibility and acceptability of the specific CFT intervention script, sampling was targeted to a local service where clients continued to receive treatment as usual. As such, there was no control group for this phase of the wider research project. This resulted in an inability to compare those accessing this intervention alongside face to face therapeutic interventions with those accessing face to face therapy alone.

Another related limitation is that information was not collected as to the content of participants' therapeutic treatment with their clinicians. Whilst this would be difficult to address given ethical considerations around client confidentiality in their treatment sessions and the fact that the research was conducted from an outside organisation (i.e. a researcher not working in the service they were engaged with), seeking consent to do so may have resulted in fewer volunteering participants. However, it does mean that we cannot ascertain from

this study whether reductions on the DASS-21 were a direct result of the CFT intervention. Nonetheless, the qualitative feedback indicates that participants attributed some of their noted improvements to be related to practicing the intervention, with comments noting “this is the only thing that’s new”.

Future Research

Despite the limited levels of control imposed in this study, it has provided valuable and promising evidence to build on in a subsequent phase of a wider research project forming a pilot-RCT, which aims to develop the CFT intervention and evaluate this with a trauma population. Whilst participants in this phase of the project may not have experienced a traumatic event(s), they were engaged with services who offer treatment for a variety of mental health difficulties, including anxiety and depression and interpersonal difficulties. As such participants were likely to have experienced some of the symptoms discussed in the extended background literature which are often co-morbid with traumatic stress (Mayou, Bryant, & Ehlers, 2001; Resick & Schnicke, 1992).

The self-help literature continues to expand and this could offer additional support for further exploration as to the benefits of this five-minute self-practice CFT intervention. Indeed, offering this more widely to additional service sites, adopting a more controlled study design, would add to both the CFT and self-help literature in clinical settings. It would therefore be useful as a next step to evaluate this more widely as an adjunct to other psychotherapeutic interventions, perhaps to those on waiting lists in mental health and community forensic services on a larger scale.

Phase Two: Extended Methods

Design

Phase two employed an RCT with a cross-over design between two groups; a CFT intervention group versus a waiting-list control group (forming a passive delayed-intervention control group). The cross-over design meant that a potentially beneficial intervention was not being withheld from any client on the trauma service waiting list, but the waiting list control group were delayed (by a three week block) in receiving the CFT script. This enabled analyses of the effects of the intervention as well as considering influences of simply having involvement in an intervention study (non-specific effects). Following the end of the initial block, participants who formed the waiting-list control group then engaged in the active intervention, whilst the active group continued to remain on the waiting list.

To allocate participants to one of the two groups single-blind blocked-randomisation was employed. Therapists did not know of clients' randomisation, and the clients were only informed if they were starting the intervention straight away or if there was a delay. I did however know of the group to which participants were assigned in order to give them the CFT intervention at the appropriate time. Blocked randomisation (Saghaei, 2004) was utilised to allocate participants using a one-to-one ratio with block sizes of four and two using approved web-based software (Urbaniak & Plous, 1997). Blocked randomisation allowed for similar if not equal size comparison groups (Schulz & Grimes, 2002) and controlled for the availability of participants over time from the trauma service waiting list. The use of different sized blocks meant that, as recruitment was consecutive, the two groups could still result in reasonably equal sizes depending on the number of participants reached.

The three week blocks were determined based on the previous use of the CFT self-practice by McEwan and Gilbert (2016). The previous study had found effects over two weeks, as did the feasibility study in this project. However, given that the waiting list at the trauma service was up to 18 weeks, and the literature reports higher levels of self-criticism and lower HRV in traumatised

individuals (Guédon-Moreau et al. 2012; Lee, 2005; Lee & Theus, 2012), it was felt that extending this to three weeks may support their practice of a novel intervention.

Phase two included eight independent variables (IV); self-compassion, self-criticism, fear of compassion, social safeness, PTSD symptom severity, associated symptoms (depression, anxiety and stress), posttraumatic growth and HRV. These were focused on as a result of the literature around the potential moderating and mediating effects these concepts have on the development and maintenance of traumatic stress.

Recruitment

Participants were recruited from the Centre for Trauma, Resilience and Growth (CTRG) in Nottingham, which provides assessment and treatment for individuals in the community suffering with traumatic stress. Referrals come from a number of sources including Combat Stress (a charity organisation for veterans), GPs and other mental health services. The aim was to recruit up to 40 participants from those who were on a waiting list for trauma-specific therapy.

Participants were eligible to take part in the project if they were met the criteria as stated in the journal paper. The need to understand verbal and written English language was due to resources. The adapted intervention was not translated into other languages.

Inclusion criteria were primarily implemented via local collaborators at the CTRG and discussions with me. The clinicians were responsible for making decisions as to which clients were appropriate for their waiting list (as opposed to being unsuitable for the service or requiring urgent intervention). In addition, they had first contact and so would be able to identify if clients could understand verbal and written English.

Power Calculations

The main objectives of the project can be analysed using a 2 x 3 mixed ANOVA, with time (baseline, mid-intervention, post-intervention) as a within-subject factor and group (CFT vs waiting list) as the between-subjects factor. The DASS-21 (Lovibond & Lovibond, 1995) was the primary outcome measure. This is planned to be extended when follow up data becomes available for participants offering an additional time point of post TAU measures.

An a priori power calculation was obtained using G*Power 3.1.9 software (Faul, Erdfelder, Buchner & Lang, 2009). With the DASS-21 (Lovibond & Lovibond, 1995) as the primary outcome measure, the average effect size of a brief CFT intervention on the DASS-21 was equivalent to a large effect size *f* of .74 (McEwan & Gilbert, 2016). An average estimate of test-retest reliability is 0.77 (Brown, Chorpita, Korotitsch & Barlow, 1997).

The initial research power calculation took into account the time point of follow up data and in that case the number of groups (2) and the number of repetitions (4), with an assumed test-retest reliability of .77, a sample size of at least 16 (8 per group) was required to provide sufficient power (80%) to detect an effect of similar magnitude (*r* = .59) at an alpha level of .05. Due to limits on timescales and the potential for follow up data being unavailable, the repetitions of measures was reduced to three. However this did not impact on the power calculation.

Following the feasibility study in phase one, it was considered appropriate to re-calculate the power based new on data for a clinical sample. The feasibility phase demonstrated a large effect size and based on the number of groups in the design for stage two (2) and repetitions (3), with a test-retest reliability of .93 (as found in the pilot study), the minimum required sample size was reduced to 8 (4 per group) to detect an effect of similar magnitude (*r* = .83).

Average attrition rates for clients with PTSD are approximately 20%, although rates vary up to 48% (Imel, et al., 2013). A cautious 60% (approx.) attrition rate

was considered given that the research was additional to participants' involvement at the trauma service. In addition, allowance for a more moderate effect size was considered, given that the intervention has not previously been trialled with a trauma population. This is also recommended by Cohen (1992) for studies where there is little previous research in the area. As the intervention itself was novel, this was deemed appropriate. Recruitment was conducted consecutively and continued until more than this minimum sample reached.

Procedure

Therapists at the CTRG were provided with detailed information about the research via a presentation at a peer supervision group, email, and personal discussions. Information sheets with my contact details were also provided to therapists to give to their clients at their assessment sessions. Verbal consent was obtained by the clinicians during assessment sessions to allow me to contact potential participants to discuss the project further. Clients who were deemed to need therapy straight away, or deemed unsuitable for the service, were not approached regarding the research. As part of the screening assessment completed by therapists, routine assessments (outlined in the 'Measures' section of the report) were completed where possible. For some clients, these were completed in their initial research appointment if the therapist had not had time to administer them. All other measures were completed in research appointments with the clients.

For those who were interested in taking part, the opportunity to ask questions was provided and aspects of the information sheet were clarified where required. Participants then signed the consent form and completed the initial research measures. They were allocated to the CFT or waiting-list condition using the blocked randomisation. All participants had a measure of their HRV taken at each of the three appointments where questionnaires were completed.

The CFT intervention script was provided in both written and audio (CD) format and participants were asked to practice this over a three-week period on a daily basis. They were provided with a record sheet to support them in writing down

when they practiced and any comments they had about it at the time. This then formed part of the feedback for their involvement in the research during their final appointment. All participants were able to keep the CD and written scripts following their involvement and were encouraged to continue practising if they so wished.

Participants were then invited to a final appointment at the end of the six weeks where they were asked to repeat all assessment measures and provide feedback on their CFT practice (appendix L). For those allocated to the immediate intervention group, they provided this feedback following the initial three week block.

Measures

Demographic questionnaire. As part of the initial assessment appointment demographic data were collected where possible. This included participant's age, gender, ethnic background, diagnoses, current medication, time since their traumatic experience and previous therapies engaged in. For the time since trauma, information was collected in relation to the traumatic event which they felt most troubled them currently, whether this was the most recent event or not.

Additional DASS-21 information. Staff at the trauma service agreed to implement the DASS-21 as a routine measure at screening assessments where possible. Where these were not completed, measures were taken in the initial research appointment following consent being obtained. This was considered an appropriate measure for this study given the literature associating depression, anxiety, and stress as highly co-morbid with traumatic stress (Kessler et al., 1995) and it's short administration time. Given the number of measures required of participants to complete, overall time and burden was kept to a minimum. Ratings on the DASS-21 indicate how frequently the individual has experienced symptoms in the past week.

Additional IES-R information. The IES-R (Weiss & Marmar, 1997) is an extension of the original IES (Horowitz, Wilner & Alvarez, 1979) which captured additional aspects of the DSM-IV criteria for PTSD. The original IES included avoidance and intrusion subscales, whilst revision added the hyperarousal subscale. The IES-R is easily accessible for use and is relatively short in administration time when compared to other measures of trauma symptoms. When analysing data from the IES-R, it is recommended to use mean scores for the subscales, and the sum of scores for the total score (Weiss & Marmar, 1997). Completing the questionnaire requires individuals to rate how distressing a list of difficulties has been for them over the past seven days. This captures time-limited data relating to current experiences of distress.

This measure is routinely used by the trauma service and is a useful outcome measure for therapy due to its sensitivity to change (Corcoran, 1994). Participants may have completed multiple IES's if they have experienced several traumatic events and therefore were given the choice of which was used in the study. They were encouraged to rate the assessment based on the traumatic experience they felt causes them the most current distress. For those who were unable to complete the IES-R during their initial trauma service assessment session, this was completed in the initial research appointment along with the other measures.

Additional PWB-PTCQ information. This measure addresses the concept that posttraumatic growth can be viewed as an increase in psychological wellbeing (Joseph & Linley, 2005). The PWB-PTCQ built on existing measures of posttraumatic growth measures (e.g. PTGI; Tedeschi & Calhoun, 1996). One of the benefits suggested by the authors is the ability to now measure both positive and negative changes following traumatic experiences (Joseph & Linley, 2005; Regel & Joseph, 2010). Following validation of the measure, it was proposed that this provided a complementary measure for use in clinical settings to symptoms measures often used routinely (Joseph, et al., 2012).

Additional FSCRS information. The concept of self-criticism was important to measure given the potential moderation effects on the maintenance of trauma symptoms. As such it was important to capture participants' levels of self-criticism as a way of evaluating the moderating impact this may have on their outcomes following the CFT intervention.

The inadequate-self subscale encompasses feeling defeated and defective, whereas the hated-self subscale focused predominantly on feeling angry and disgusted with oneself (Gilbert, et al., 2004). The self-reassurance scale is indicative of positive and warm outlook towards oneself (Gilbert, et al., 2004).

Additional FOC information. The FOC scales (Gilbert et al. 2011) consider thoughts and beliefs in relation to compassion in three areas: compassion for others, compassion from others and expressing compassion towards self. Permission has been granted by the authors for researchers to use the self-compassion subscale in isolation for research project purposes. The fear of compassion-for-self subscale has been found to be significantly linked with self-criticism (Gilbert et al. 2011). This subscale contributes to a set of three self-report measures looking at fear of compassion (to self, *to* others, and *from* others). It was found in that in both student and therapist samples, fear of compassion was related to self-criticism and depression (Gilbert, et al., 2011).

Additional SCS-SF information. The current study utilised the 12-item shortened version as an efficient alternative to the SCS (Raes, et al., 2011). Research has adopted varying ways of scoring the SCS. Some use a total SCS score (MacBeth & Gumley, 2012) whilst others advocate generating a mean score for a positive self-compassion subscale (comprised of three of the six components in the measure: self-kindness, mindfulness and common humanity) and a mean score for the for a negative self-compassion subscale (self-judgement, over-identification, and isolation referred to as 'self-coldness' within the SCS (Gilbert, et al., 2011). The SCS-SF has demonstrated sensitivity to change following self-compassion interventions (Neff & Germer, 2012) and

aimed to capture increases in participants' ability to be self-compassionate following the CFT intervention.

It has been argued that the overall total is less meaningful than the two subscales noted above, as fMRI results have demonstrated that positive feelings of compassion and negative feelings relating to threat are not a unitary concept when exploring brain imaging (Longe, et al., 2010). However internal consistencies for the six subscales were low and therefore when using the SCS-SF, it is recommended that total scores be used (Raes, et al. 2011). As self-compassion broadly was the phenomena of interest in this study, rather than each component comprising it, as well as caution against participant burden, the use of the SCS-SF and total mean scores was deemed appropriate.

Additional SSPS information. The validation of the SSPS measure was completed with a sample of students and a sample of patients diagnosed with bi-polar disorder (Gilbert, et al., 2009). Out of their research they concluded that experiences of social safeness may be impacted by feelings of inferiority compared to others (i.e. in terms of social rank or status). In addition, Gilbert (2010) reported that social safeness was negatively correlated with depression and anxiety. Social safeness is considered a separate emotional state to feeling less threatened, that is, the positive feelings associated with social safeness are more than just an absence of negativity (Kelly et. al., 2012). The measure allows for consideration as to any moderating effect of affiliative and soothing experiences of others.

Additional HRV measurement information. Traditionally, measures of HRV are taken by electrocardiographic (ECG) recorders (Task Force, 1996) from which data is recorded and analysed using computer software (Sandercock, Shelton, Bromley & Brodie, 2004). However, new or clinical environments can increase hypervigilance (Porges, 2011) and the use of alternative validated measures may be more appropriate. The Polar S810 Heart Rate Monitor (HRM) demonstrates excellent agreement with ECG measures (Gamelin, Baquet, Berthoin & Bosquet, 2008; Sandercock, et al. 2004; Weippert

et al. 2010). The watch utilised in the study was the Polar RS800CX, which is an updated version of the previously validated Polar heart rate monitor. This model is described by manufacturers as an improved version and therefore it is assumed the measurement process and the output provided by the watch in relation to HRV remained valid. Full fitting instructions for the watch and chest strap were provided to allow participants to complete this procedure with privacy and dignity. This was then worn throughout the appointment with the primary researcher. Data was uploaded to a secure laptop using software supplied with the device. Data was then further analysed using graphical representations of the time series through Polar ProTrainer 5 software and SPSS for Windows.

Recommendations for minimising anxiety when taking HRV measurements (in order to obtain the most accurate data reflecting calm state HRV) are to provide a pleasant atmosphere and to offer full instructions as to what HRV is and how data is collected (Frustaci, et. al., 2010). During appointments with participants they were informed that HRV was the measurement of beat-to-beat changes in heart rate. It was made clear that their resting heart rate was not what the study was focused on and that no medical information or advice could or would be offered in relation to observe HR or HRV on the watches. This was on the basis that I do not have the relevant medical expertise to do so and this was not the purpose of the research. All participants were able to ask any questions and have the option to have a HRV measurement taken or not. This was given as an option as it was not the primary research variable and was potentially the most invasive aspect of the study. No participants declined.

Phase Two Extended Analysis.

The outcome data for this phase included categorical and interval data. Quantitative demographic data included binary, and categorical data and questionnaires provided interval data for analysis.

Assumptions

The assumptions required to be met for analysis of variance (specifically a two-way mixed ANOVA) are for data to include one independent variable (in this

case the DASS-21 and for subsequent analyses the independent variable would be each additional questionnaire) and one between-subjects variable which is categorical with a minimum of two categories (in the pilot RCT this was immediate or delayed CFT group). One within-subjects factor that is categorical is also required, in this case it is time (pre, mid, and post intervention).

As with phase one of the project, to test for normal distributions on the subscales, the Shapiro-Wilk test of normality was employed (pertaining to the small sample size) as well as the addition of assessment of skewness and kurtosis z-scores.

Analysis of variance

To test the hypotheses of decreases in DASS-21 scores following CFT intervention, a two-way mixed design ANOVA was conducted. Two-way mixed ANOVA analysis enables establishment of the presence of interactions between a between-subjects variable and a within-subjects variable on a dependent variable. This enables calculation of whether either the between- or within-subjects factors have an effect on the dependent variable, but also whether there is an interaction between them on it. Following statistical analysis using a two-way mixed ANOVA, significant interactions can be further explored via simple main effects and, in the case of this study, non-significant results can be explored via main effects. Given the number of variables tested in this study, Bonferroni corrections were applied. This post hoc test is considered robust for ANOVAs where required assumptions, such as sphericity are violated (Field, 2009).

Phase Two: Extended Results

Participants

A total of 21 participants demonstrated an interest in the research with 14 completing the initial appointment. Those who did not attend an initial appointment did not engage when their expressions of interested were followed up. Three other individuals withdrew within the first three weeks: one due to medical health concerns which arose; one participant stated that it was no longer the right time and they felt unable to engage; one participant did not

provide reasons. A further one participant withdrew following the mid-point, after experiencing an increase in their PTSD symptoms due to a triggering event (unrelated to their participation), which led to an in-patient admission.

Missing Data

There was no missing data from questionnaires completed by the final 10 participants. HRV data was missing for two participants due to technological errors in the settings configured on the Polar watches. As such, this meant that for two participants, only heart rate (beats per minute) was collected during all three assessment appointments. No R-R curve data were available and therefore they had to be excluded from the HRV data analysis.

For the four participants who withdrew from the study, only initial assessment measures were obtained for the data set. As a result of the limited data available for use, and as the study was a pilot RCT providing an early exploration in this area, intention to treat analysis were not conducted. The study provides an initial scoping in to the study design and intervention outcomes. It offers a first attempt to establish likely attrition rates and further studies would benefit from more rigorous and larger scale RCT designs.

Outliers

Boxplots were produced in order to visually explore the data for outliers. These identified 12 outliers across the various subscales and total score on the DASS-21 (see figures 6 & 7), 17 outliers across the IES-R subscales and total scores (figure 8 & 9), two outliers on the PWB-PTCQ measure (figure 10), seven outliers across the FSCRS subscales (figure 11), five outliers on the SCS (figure 12), one outlier on the SCS (figure 13) and one extreme outlier for measurements relating to HRV with the exception of mean R-R interval data (figures 14 & 15). This outlier impacted on the normality of data and the decision was made to remove it. For all other measures, outliers remained due to the high number of outliers and low sample size. There were no outliers on the FOC measure. Where outliers were indicated, the data was checked for errors, of which none were identified.

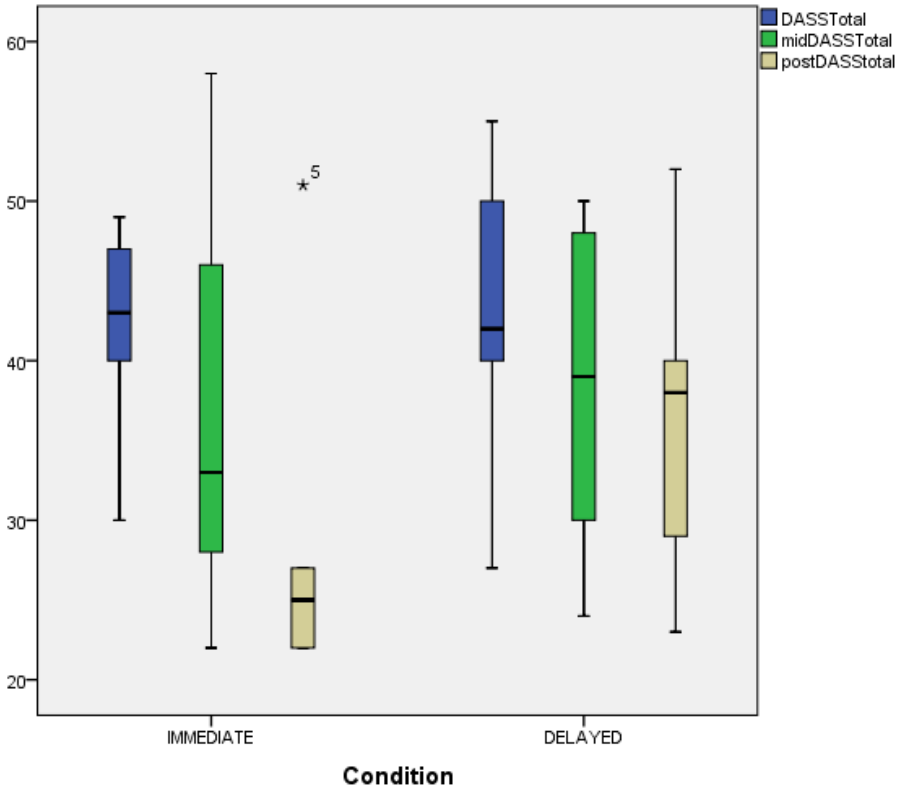

Figure 6. Boxplot representing outliers for the DASS-21 total scores.

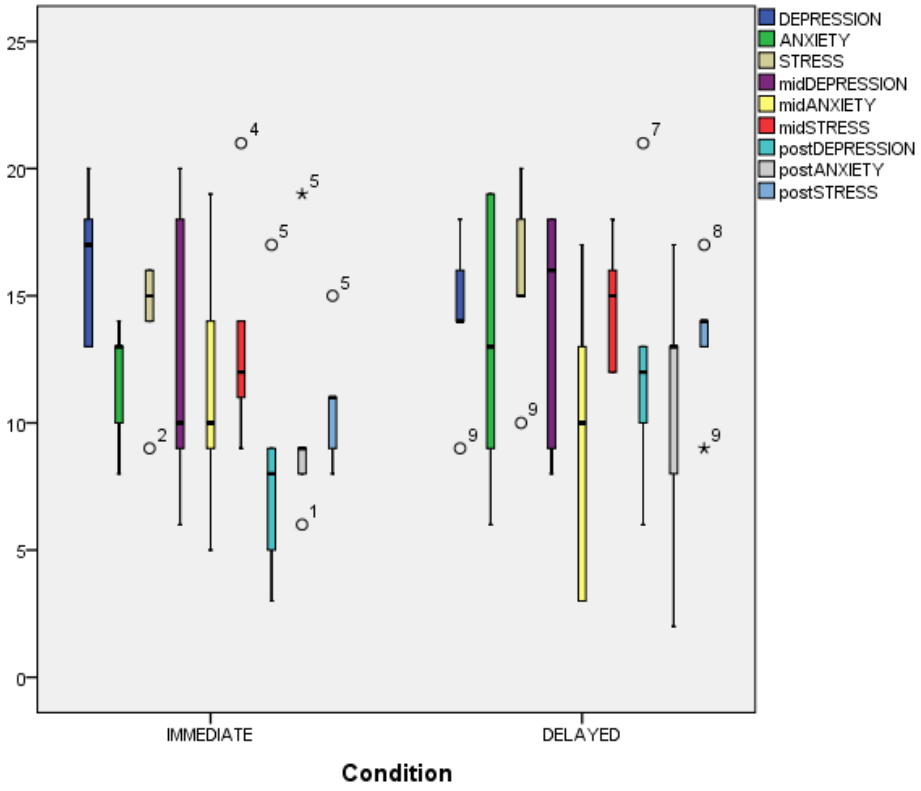

Figure 7. Boxplot representing outliers for the DASS-21 subscale scores.

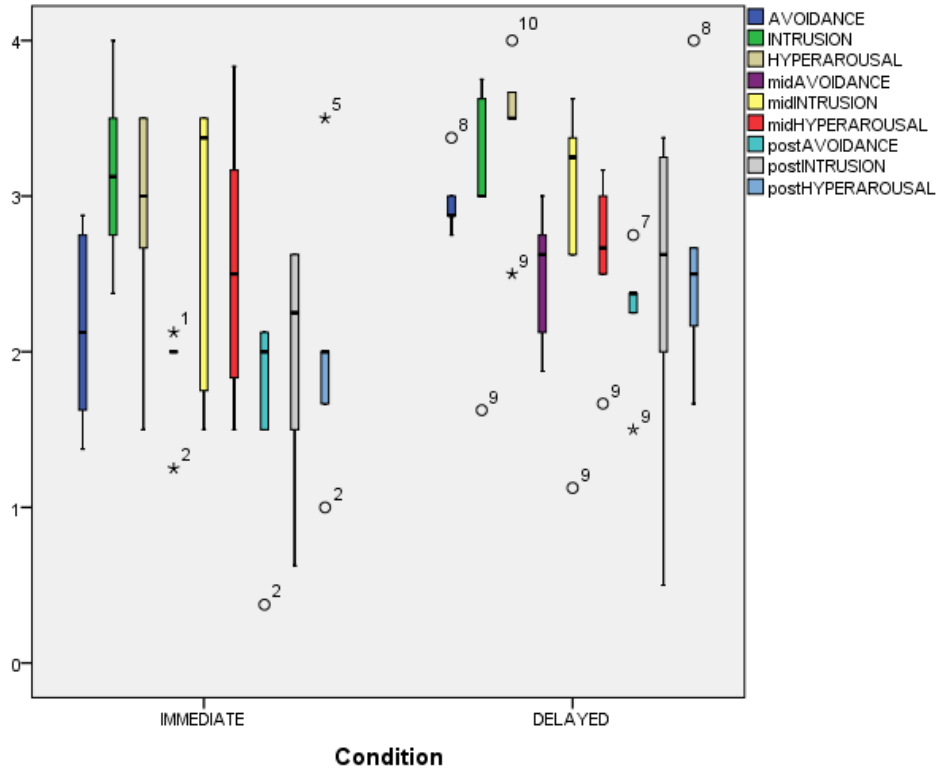

Figure 8. Boxplot representing outliers for the IES-R subscale scores.

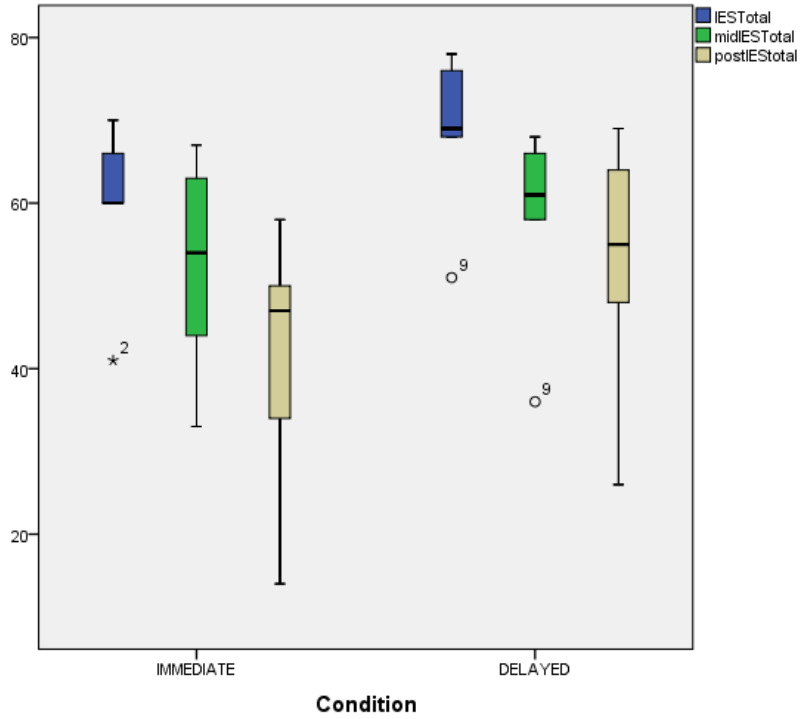

Figure 9. Boxplot representing outliers for the IES-R total scores.

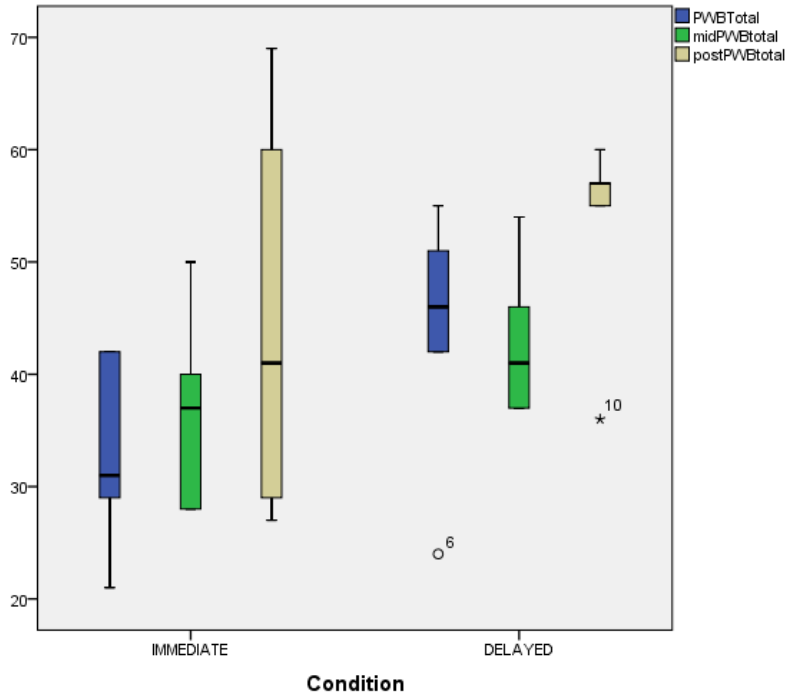

Figure 10. Boxplot representing outliers for the PWB-PTCQ total scores

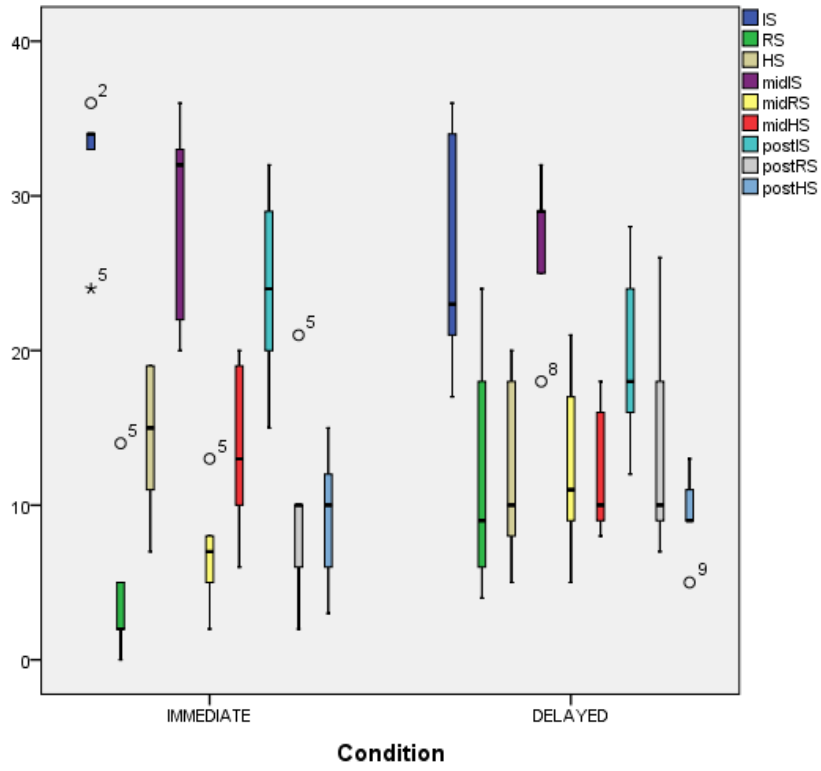

Figure 11. Boxplot representing outliers for the FSCRS subscale scores

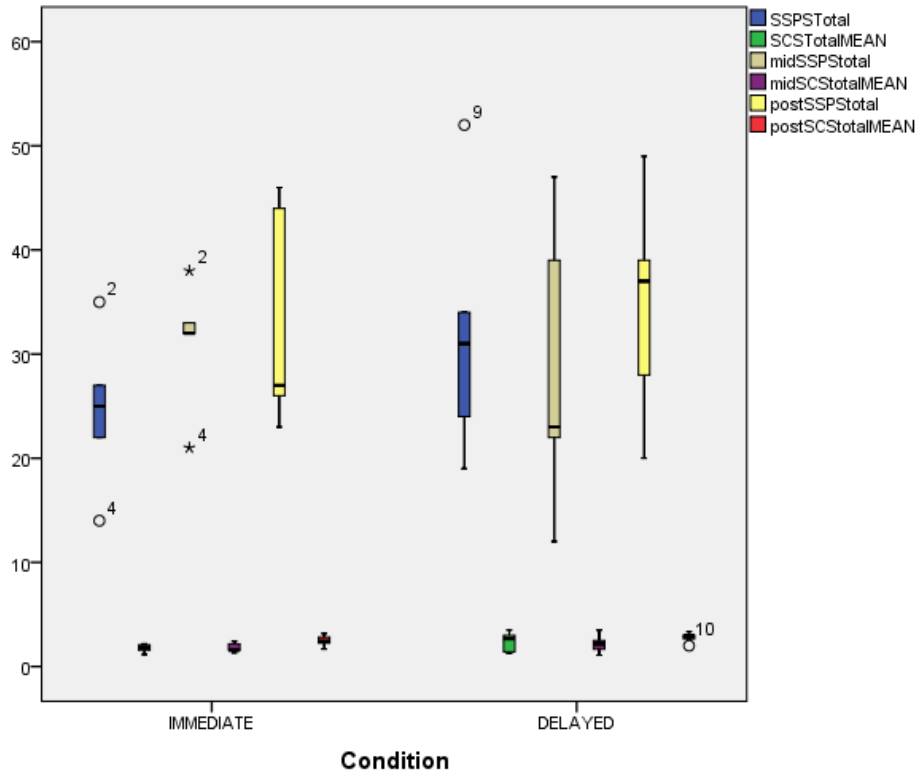

Figure 12. Boxplot representing outliers for the SSPS and SCS total scores.

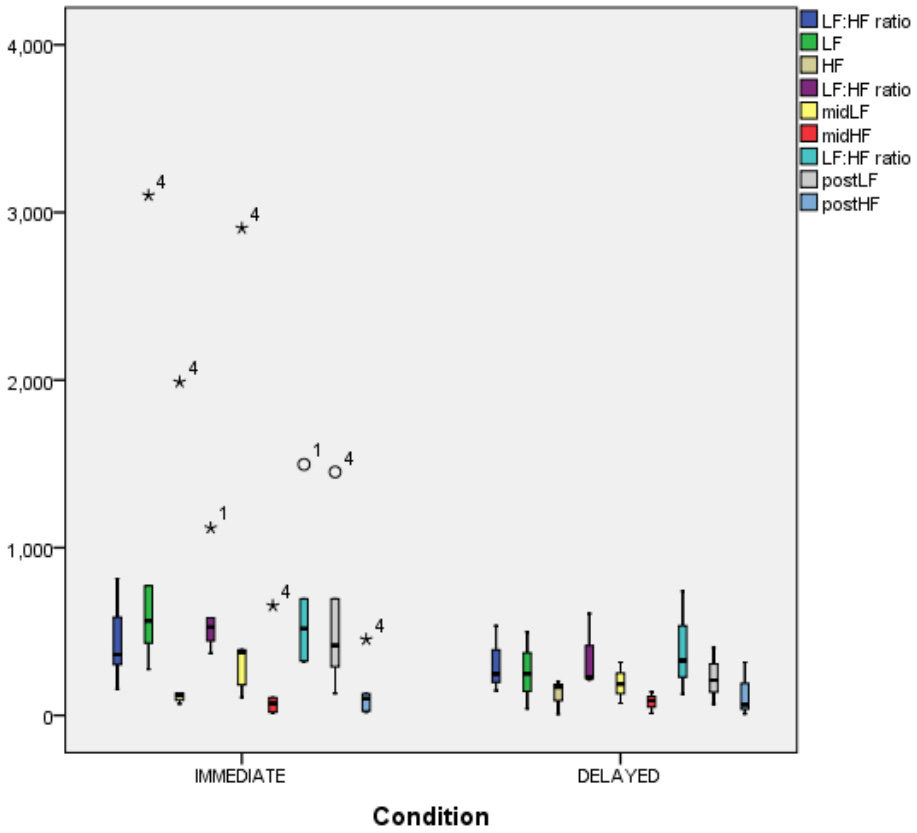

Figure 13. Boxplot representing outliers for the LF:HR ratios, Low Frequency and High Frequency HRV measurements.

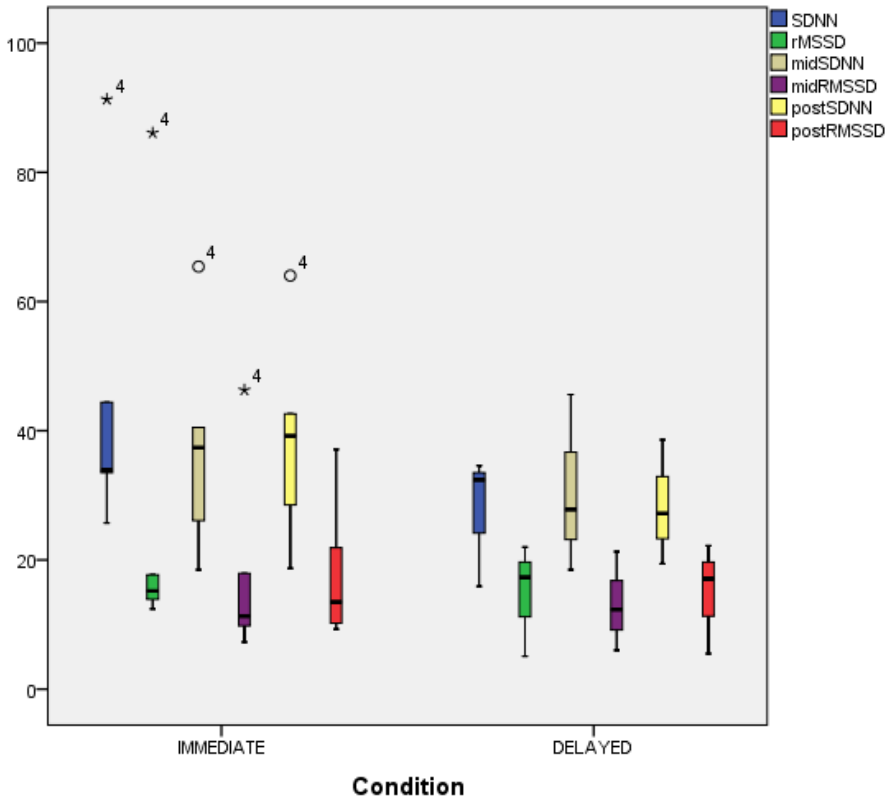

Figure 14. Boxplot representing outliers for the SDNN, and rMSSD HRV measurements.

Tests of Normality

The assumption of normal distribution must be met in order to apply parametric tests. The Shapiro-Wilk test offers assessment of whether a sample is normally distributed. This is chosen instead of the Kolmogorov-Smirnov test as it is recommended for samples sizes of less than 50 (Laerd Statistics, 2016). A non-significant test result indicates that the distribution of the sample on the tested variable is normal. Each variable was analysed using this method. These analyses revealed that normality assumptions were violated by several assessment variables;

DASS-21: normality was violated in the immediate group on the pre-intervention stress subscale ($D(5) = .698$, $p = .009$) and the post-intervention anxiety subscale ($D(5) = .767$, $p = .043$) and total score ($D(5) = .698$, $p = .009$);
FSCRS: the immediate group was significantly non-normal on the pre-intervention inadequate-self subscale ($D(5) = .760$, $p = .037$);

IES-R: normality was violated in the immediate group on the mid-point measures of the avoidance (*D*(5) = .676, *p* =.005) and intrusion (*D*(5) = .753, *p* =.032) subscales and on the post-intervention avoidance scale (*D*(5) = .778, *p* =.053);

PWB-PTCQ: the delayed intervention group demonstrated significant violation of assumptions on the post-intervention score (*D*(5) = .722, *p* =.016);

FOC: the immediate group were significantly non-normal on the post FOC score (*D*(5) = .756, *p* =.033).

A further test of normality was obtained using the z-score values of the skewness and kurtosis of the data. Varying recommendations are given for skewness and kurtosis. Field (2009) recommends taking a value of ±1.96, although it is also argued that more conservative values of ±2.58 as the boundaries for demonstrating significant non-normality. Taking a conservative approach, all variables for the immediate group could be considered normally distributed based on the skewness and kurtosis z scores. Similarly, all variables for the delayed intervention group could be considered as normally distributed.

If taking the stricter criteria for skewness and kurtosis, then several measures in the immediate intervention group fell outside the assumptions for normality, supporting the Shapiro-Wilk findings.

DASS-21: normality was violated in the immediate group on the pre-intervention stress subscale, with a z-score of skewness of -1.99 and a z-score of kurtosis of 1.69. For the post-intervention anxiety subscale the z-score of skewness was 2.08 and the z-score of kurtosis was 2.00, and for the post-DASS-12 total score the z-score of skewness was 2.27 and the z-score of kurtosis was 2.20.
FSCRS: the immediate group was significantly non-normal on the pre-intervention inadequate-self subscale with a z-score of skewness of -2.11 and a z-score of kurtosis of 2.03.

IES-R: For the immediate group on the mid-point measures of the avoidance the z-score of skewness was -2.38 and the z-score of kurtosis was 2.29, however none of the other assessment points for this variable fell outside of the range for acceptable normal distribution.

PWB-PTCQ: the delayed intervention group demonstrated violation of assumptions on the post-intervention score with a z-score of skewness of -2.24 and a z-score of kurtosis of 2.18.

None of the other variables demonstrated z-scores of skewness or kurtosis outside of these ranges.

Additional ANOVA assumptions. When running analysis of variance, as well as testing for normality and outliers, other assumptions must be met.

Homogeneity of variances. This was checked for all measures using Levine's test for equality of variance. This was non-significant for all measures, with the exception of pre-intervention IES-R avoidance scores (p = .042), pre-intervention HF HRV scores (p = .3), and mid-intervention scores for the SSPS scale (p = .049). For the remaining variables this assumption was met. As the analyses were exploratory at this stage, data transformation for these variables was not conducted. Given that not all time points for the variables violated the data, transforming them may have generated negative consequences on the other time points where data met the required assumptions.

Homogeneity of covariances. This was tested for using Box's test of equality of covariance and indicated that this assumption was not violated for any of the measures.

Assumption of sphericity. The assumption to be met is to determine that the differences between groups should be equal. This refers to the variances of the difference between the groups, assessed by Mauchly's test of sphericity.

Tests identified that sphericity assumptions were met for all variables with the exception of the hated-self subscale of the FSCRS and the PWB-PTCQ. For these variables the Greenhouse-Geisser statistics were interpreted instead of those where sphericity would ordinarily be assumed.

Additional descriptive data. Table 11 shows descriptive statistic data for all of the subscales and total scores (where applicable) for all of the measures at the initial measurement point. This data includes the extreme outlier on the HRV measures. Cronbach's alpha levels are also provided for the scales. All scales and subscales measured can all be considered good in terms of their internal consistency (Kline, 2013), with the DASS-21 Depression and the IES-R Avoidance subscales falling slightly below the recommended α= .7. On closer inspection, deleting items from either of the two scales would not result in a greatly different Cronbach's alpha; the largest that could be gained for the IES-R avoidance was .72 taking it just into the accepted range, and for DASS-21 Depression subscale it could be adjusted to .69. Due to the relatively small changes these were not omitted, but consideration was borne in mind when interpreting results.

Table 11. Descriptive data for scales at pre-intervention.

Subscale/Scale	*M*	*(SD)*	α
DASS-21 Depression (n=10)	15.20	3.22	.60
DASS-21 Anxiety (n=10)	12.40	4.33	.76
DASS-21 Stress (n=10)	14.80	3.29	.75
DASS-2 Total (n=10)	42.30	8.72	.83
IES-R Avoidance (n=10)	2.56	0.64	.63
IES-R Intrusion (n=10)	3.08	0.71	.85
IES-R Hyperarousal (n=10)	3.13	0.74	.87
IES-R Total (n=10)	63.90	11.31	.84

Subscale/Scale	*M*	*(SD)*	α
PWB-PTCQ (n=10)	38.30	11.47	.87
FSCRS – inadequate (n=10)	29.20	7.13	.88
FSCRS – hated (n=10)	13.20	5.65	.78
FSCRS – reassure (n=10)	8.40	7.86	.89
FOC Total (n=10)	39.20	7.74	.71
SSPS Total (n=10)	28.30	10.58	.94
SCS Mean Total (n=10)	2.07	0.78	.82
Mean R-R (ms) (n=8)	775.25	179.34	-
SDNN (ms) (n=8)	38.96	22.66	-
rMSSD (ms) (n=8)	23.71	25.66	-
LF (ms^2) (n=8)	740.96	979.38	-
HF (ms^2) (n=8)	346.96	665.96	-
LF: HF (%)(n=8)	394.15	234.00	-

***ANOVA:* Non-significant Results**

DASS-21. For DASS-21 Depression scores, there were no significant interaction effects $F(2, 16) = 1.833$, $p = .192$, partial $\eta^2 = .186$. Significant main effects of time suggested that changes on this subscale were associated with time. The unweighted marginal means of depression scores for pre, mid, and post-intervention measurements were 15.2 (*SE* = 1.02), 13.20 (*SE* = 1.75), and 10.40 (*SE* = 1.72), respectively. However, pairwise comparisons did not identify any significant differences in mean scores between time points. The nearest to significance showed pre-intervention (T_1) was associated with a mean DASS-21 depression score 4.80, 95% CI [-.242, 9.84] points higher than post-intervention (T_3), $p = .062$.

For DASS-21 Anxiety scores, there were no significant interaction effects between time and condition, $F(2, 16) = .691$, $p = .515$, partial $\eta^2 = .080$, nor were there significant main effects of time $F(2, 16) = 1.028$, $p = .380$, partial $\eta^2 = .114$. There were no significant effects of group $F(1, 8) = .001$, $p = .981$, partial $\eta^2 = .000$.

For DASS-21 Stress scores, there were no significant interaction effects between time and condition, $F(2, 16) = .166$, $p = .849$, partial $\eta^2 = .020$, nor were there significant main effects of time $F(2, 16) = 2.450$, $p = .118$, partial $\eta^2 = .234$. There were no significant effects of group $F(1, 8) = 1.389$, $p = .273$, partial $\eta^2 = .148$.

For DASS-21 total scores, there were no significant interaction effects between time and condition $F(2, 16) = .412$, $p = .669$, partial $\eta^2 = .049$. In addition the effect of time was also non-significant $F(2, 16) = 2.933$, $p = .082$, partial $\eta^2 = .268$. There were no significant effects of group $F(1, 8) = .269$, $p = .618$, partial $\eta^2 = .033$.

IES-R. For IES-R Avoidance subscale scores, there were no significant interaction effects between time and condition, $F(2, 16) = .217$, $p = .808$, partial $\eta^2 = .026$. Significant main effects of time were found. The unweighted marginal means of avoidance scores for pre, mid, and post-intervention measurements were 5.56 ($SE = .158$), 2.18 ($SE = .130$), and 1.94 ($SE = .196$), respectively. However, pairwise comparisons did not identify any significant differences in mean scores between time points. The nearest to significance showed pre-intervention (T_1) was associated with a mean IES-R avoidance score .625, 95% CI [-.036, 1.286] points higher than post-intervention (T_3), $p = .064$.

For IES-R Intrusion subscale scores, there were no significant interaction effects between time and condition, $F(2, 16) = 1.244$, $p = .315$, partial $\eta^2 = .135$. There were no significant effects of group $F(1, 8) = .045$, $p = .838$, partial $\eta^2 = .006$.

For IES-R Hyperarousal subscale scores, there were no significant interaction effects between time and condition, $F(2, 16) = 1.058$, $p = .370$, partial $\eta^2 = .117$. There were no significant effects of group $F(1, 8) = .831$, $p = .389$, partial $\eta^2 = .094$.

For IES-R total scores, there were no significant interaction effects between time and condition, $F(2, 16) = .546$, $p = .590$, partial $\eta^2 = .064$. There were no significant effects of group $F(1, 8) = 1.165$, $p = .312$, partial $\eta^2 = .127$.

PWB-PTCQ. For the PWB-PTCQ total scores, there were no significant interaction effects between time and condition, $F(2, 16) = .110$, $p = .784$, partial $\eta^2 = .014$, nor were there significant main effects of time $F(2, 16) = 3.293$, $p = .099$, partial $\eta^2 = .292$. Effects of group were also non-significant $F(1, 8) = 2.653$, $p = .143$, partial $\eta^2 = .248$. Greenhouse-Geisser statistics were interpreted due to violations of sphericity.

FSCRS. For the inadequate-self subscale scores, there were no significant interaction effects $F(2, 16) = .524$, $p = .602$, partial $\eta^2 = .062$. There were no significant effects of group $F(1, 8) = 1.409$, $p = .269$, partial $\eta^2 = .150$.

For the reassure-self subscale scores, there were no significant interaction effects between time and condition, $F(2, 16) = .295$, $p = .749$, partial $\eta^2 = .036$, nor were there significant main effects of time $F(2, 16) = 1.254$, $p = .312$, partial $\eta^2 = .135$ or of group $F(1, 8) = 2.900$, $p = .127$, partial $\eta^2 = .266$.

For hated self-subscale scores, there were no significant interaction effects between time and condition, $F(2, 16) = .497$, $p = .528$, partial $\eta^2 = .059$, nor were there significant effects of group $F(1, 8) = .131$, $p = .727$, partial $\eta^2 = .016$. Significant main effects of time were found. The unweighted marginal means of hated-self scores for pre, mid, and post-intervention measurements were 2.64 ($SE = .373$), 2.58 ($SE = .333$), and 1.86 ($SE = .251$), respectively. However, pairwise comparisons did not identify any significant differences in mean scores between time points. The nearest to significance showed mid-intervention (T_2)

was associated with a mean FSCRS hated-self score .720, 95% CI [-.013, 1.453] points higher than post-intervention (T_3), p = .054.

FOC. For the FOC total scores, there were no significant interaction effects between time and condition, $F(2, 16) = .124$, $p = .884$, partial $\eta^2 = .015$, nor were there significant main effects of time $F(2, 16) = 1.445$, $p = .265$, partial $\eta^2 = .153$. Effects of group were also non-significant $F(1, 8) = 2.174$, $p = .179$, partial $\eta^2 = .214$.

SSPS. For the SSPS total scores, there were no significant interaction effects between time and condition, $F(2, 16) = .166$, $p = .826$, partial $\eta^2 = .020$, nor were there significant main effects of time $F(2, 16) = 3.406$, $p = .066$, partial $\eta^2 = .29$. Effects of group were also non-significant $F(1, 8) = 2.001$, $p = .195$, partial $\eta^2 = .200$. Greenhouse-Geisser statistics were interpreted due to violations of sphericity.

HRV. For HF HRV scores, there were no significant interaction effects between time and condition, $F(2, 10) = .267$, $p = .771$, partial $\eta^2 = .051$. There were no significant main effects of time $F(2, 10) = 1.400$, $p = .291$, partial $\eta^2 = .219$ or for group $F(1, 5) = .499$, $p = .512$, partial $\eta^2 = .091$.

For LF HRV scores, there were no significant interaction effects between time and condition, $F(2, 10) = 1.214$, $p = .337$, partial $\eta^2 = .195$. There were no significant main effects of time $F(2, 10) = 3.847$, $p = .0.58$, partial $\eta^2 = .435$ or for group $F(1, 5) = 1.468$, $p = .280$, partial $\eta^2 = .227$.

For LF:HF ratio scores, there were no significant interaction effects between time and condition, $F(2, 10) = .488$, $p = .628$, partial $\eta^2 = .089$. There were no significant main effects of time $F(2, 10) = 2.253$, $p = .156$, partial $\eta^2 = .311$ or for group $F(1, 5) = 1.491$, $p = .276$, partial $\eta^2 = .230$.
For rMSSD HRV scores, there were no significant interaction effects between time and condition, $F(2, 10) = .149$, $p = .864$, partial $\eta^2 = .029$. There were no

significant main effects of time $F(2, 10) = 1.367$, $p = .299$, partial $\eta^2 = .215$ or for group $F(1, 5) = .045$, $p = .840$, partial $\eta^2 = .009$.

For SDNN HRV scores, there were no significant interaction effects between time and condition, $F(2, 10) = .636$, $p = .549$, partial $\eta^2 = .113$. There were no significant main effects of time $F(2, 10) = .026$, $p = .975$, partial $\eta^2 = .005$ or for group $F(1, 5) = .245$, $p = .642$, partial $\eta^2 = .047$.

For R-R interval scores, there were no significant interaction effects between time and condition, $F(2, 10) = .332$, $p = .725$, partial $\eta^2 = .062$. There were no significant main effects of time $F(2, 10) = 1.609$, $p = .248$, partial $\eta^2 = .243$ or for group $F(1, 5) = .070$, $p = .802$, partial $\eta^2 = .014$.

Contrasts Analyses

To further explore the significant main effects, contrasts were analysed. The comparison of interest for repeated measures was between pre and post (T_1 and T_3) assessment points. Contrasts compared all participants regardless of group at pre and post assessment. This enables comparison of effect sizes with those calculated in phase one of the study. For ease of interpretation between the results of the two phases, partial eta squared effect sizes produced in the ANOVAs have been converted to Cohen's *d*. These are summarised below;

The DASS-21 depression demonstrated significantly large differences from pre to post intervention, $F(1,8) = 8.24$, $p = .021$, $d = 1.17$. This is marginally less than the $d = 1.40$ on the DASS-21 total found in phase one, but is nevertheless a large effect size.

On the IES-R. all three subscales demonstrated large effect sizes from pre to post intervention: avoidance, $F(1,8) = 8.14$, $p = .021$, $d = 1.17$; intrusion, $F(1,8) = 23.24$, $p = .001$ $d = 2.23$, and hyperarousal, $F(1,8) = 12.57$, p = .008, d = 1.54.

The self-criticism subscales on the FSCRS also demonstrated large effects on the pre to post intervention scores: inadequate self; $F(1,8) = 17.25$, $p = .003$, $d = 1.87$, and hated self; $F(1,8) = 7.12$, p = .028, d = 1.07.

Simple contrasts at the between group level, focused on the mid-assessment time point. Analyses at T2 offered a direct observation between the control and intervention group. There were no significant differences between the groups on any measure with the exception being the IES-R avoidance subscale. However the groups differed significantly on this measure at the pre-intervention assessment and therefore this difference preceded the intervention stage. As such, it is not indicated that the significant difference is due to whether or not participants had engaged in the CFT intervention.

Moderation

Moderator variables are those that effect the direction or strength of a relationship between a predictor and an outcome variable. Hypothesis three proposed that high fear of compassion and/or high self-criticism may moderate the impact of the CFT intervention on the DASS-21 scores. However, moderation analyses at this stage were not carried out. The assumptions required for this analysis follow those set out for multiple regression. Given the exploratory nature of the ANOVA analyses for phase two and the underpowered sample, moderation analysis would not be recommended. Exploratory analysis of whether the data met assumptions for such analyses indicated that multicollinearity (representing strong correlations between predictor variables in a regression model) was problematic for the FSCRS scales and both the FOC and FSCRS demonstrated leverage points which would suggest caution as the negative effect they would have on the moderator analysis (Laerd Statistics, 2016). As a result of moderation analysis therefore not being indicated with the data available, individual level analyses were explored. Such additional analyses were considered merited due to the large differences in standard deviations from the pre- to mid-intervention assessment points of the immediate intervention group.

Reliable change. Reliable change indices (RCI; Jacobson & Truax, 1991) were calculated for the FOC total scores and the 'Inadequate-self' and 'Hated-self' subscale scores of the FSCRS from pre- to post-CFT intervention. Whilst it can be argued that applying statistical calculations to outcomes measures does not offer an evaluation of the personal meaning to the client, RCI scores are standardised measures of change and offer an objective examination of the data (Jacobson & Truax, 1991). RCI calculations offer an indication as to whether the magnitude of change for an individual is statically reliable or not, or whether it could be attributed to chance or measurement error. (See Appendix M for raw data used to inform RCI calculations).

DASS-21. The critical value for reliable change was 17.58 and as can be seen in Table 12, two participants achieved this change on the DASS-21 total score.

Table 12. DASS-21 Total Score RCI index scores

Participant	Pre-intervention Score	Post-intervention score	Change Score	RCI	CSC
1	50	38	12	1.34	-
2	42	52	10	-1.11	-
3	55	40	15	1.67	-
4	27	23	4	0.45	-
5	43	22	21	2.34*	Yes
6	40	29	11	1.23	-
7	30	22	8	0.89	-
8	49	25	24	2.67*	Yes
9	40	27	13	1.45	-
10	47	51	4	-0.45	-

NB. It is considered that an RCI value greater than ±1.96 is statistically reliable at the $p<.05$ level. *denotes significant results.

In identifying Clinically Significant Change (CSC) on DASS-21 Total scores criterion 'b' was adopted, as recommended when clinical and non-clinical norms have non-overlapping distributions (Jacobson & Truax, 1991). The cut-off score

for criterion ‘b’ was 28.75. Both of the participants who demonstrated reliable change showed clinically meaningful change scores.

Self-criticism: inadequate self*.* The critical value for reliable change was 5.88 and as can be seen in Table 13, five participants achieved this change in self-criticism IS scores.

Table 13. FSCRS IS subscale RCI index scores

Participant	Pre-intervention Score	Post-intervention score	Change Score	RCI	CSC
1	23	12	11	3.66*	Yes
2	21	18	3	1.00	
3	34	24	10	3.33*	No
4	17	16	1	0.33	
5	24	20	4	1.33	
6	36	28	8	2.66*	No
7	33	15	18	5.99*	Yes
8	34	29	5	1.66	
9	36	24	12	3.99*	No
10	34	32	2	0.67	

NB. It is considered that an RCI value greater than ±1.96 is statistically reliable at the $p<.05$ level. *denotes significant results.

As a result of the statistically reliable changes, it was considered whether these were clinically meaningful or not. In identifying Clinically Significant Change (CSC) for FSCRS IS scores criterion ‘c’ was adopted, as recommended when both clinical and non-clinical norms are provided with overlapping distributions (Jacobson & Truax, 1991). The cut-off score for criterion ‘c’ was 22.84. Two of the five participants who demonstrated reliable change can also be considered to have made clinically significant changes as a result of their post-intervention scores falling below the cut-off score of 22.84.

Self-criticism: hated self. The critical value for reliable change was 5.66 and as can be seen in Table 14, four participants achieved this change in self-criticism HS scores.

Table 14. FSCRS HS subscale RCI index scores

Participant	Pre-intervention Score	Post-intervention score	Change Score	RCI	CSC
1	10	5	5	1.73	
2	8	9	-1	-0.35	
3	18	11	7	2.42*	No
4	5	9	-4	-1.38	
5	7	3	4	1.38	
6	20	13	7	2.42*	No
7	15	6	9	3.11*	Yes
8	11	12	-1	-0.35	
9	19	10	9	3.11*	No
10	19	15	4	1.38	

NB. It is considered that an RCI value greater than ±1.96 is statistically reliable at the $p<.05$ level. *denotes significant results

As a result of the statistically reliable changes, it was considered whether these were clinically significant or not. In identifying Clinically Significant Change (CSC) for FSCRS HS scores, again criterion ‘c’ was adopted. The cut-off score for criterion ‘c’ was 7.63. One of the four participants who demonstrated reliable change can also be considered clinically significant as a result of their post-intervention scores falling below the cut-off score of 7.63.

FOC. The critical value for reliable change was 8.14 and as can be seen in Table 15, six participants achieved this change in FOC scores.

Table 15. FOC Total RCI index scores

Participant	Pre-intervention Score	Post-intervention score	Change Score	RCI	CSC
1	34	45	-11	-.2.65^	
2	25	20	5	1.20	
3	43	12	31	7.47*	Yes
4	37	24	13	3.13*	No
5	39	20	19	4.58*	No
6	47	38	9	2.17*	No
7	46	25	21	5.06*	No
8	50	52	-2	-0.48	
9	40	21	19	4.58*	No
10	31	52	-21	-5.06^	

NB. It is considered that an RCI value greater than ±1.96 is statistically reliable at the $p<.05$ level. *denotes significant results. ^ denotes deterioration.

In identifying Clinically Significant Change (CSC) on FOC scores criterion 'b' was adopted, as recommended when clinical and non-clinical norms have non-overlapping distributions (Jacobson & Truax, 1991).No clinical norms could be found in the literature and only the non-clinical data available was used. As a result, criterion 'c' was adopted for assessing CSC. The cut-off score for criterion 'c' was 16.12. Only one of the participants who demonstrated reliable change showed clinically meaningful change scores with their post-intervention score falling below the cut-off score.

Phase Two: Extended Discussion

Non-significant ANOVAs.

Previous research has demonstrated significant positive effects of compassionate based intervention on symptoms of depression and anxiety (McEwan & Gilbert, 2016; Neff & Germer, 2012). However, contrary to hypothesis one, the CFT intervention did not demonstrate significant symptom reduction on the DASS-21. Nor did it find significant reductions on the FSCRS. Hypothesis two was also unsupported as no significant interaction effects were

found for HRV, self-compassion or social safeness, indicating that the CFT intervention did not effectively impact these factors. Moderating factors, specifically fear of compassion and self-criticism are discussed under 'reliable change index analyses'.

Whilst the two groups did not demonstrate significant differences on the majority of the measures, there were notable differences in the avoidance symptoms experienced between the two groups. The delayed intervention group demonstrated higher levels of IES-R avoidance symptoms across time points. The lower internal consistency demonstrated for this sample on the IES-R avoidance subscale suggests that this measure may have been tapping into constructs or symptoms other than purely avoidance, perhaps to a broader level of distress relating to trying to avoid traumatic reminders. However an additional consideration might be related to whether those scoring higher on avoidance may have been more likely to experience fear of compassion (and thus want to avoid it). However the FOC scores did not indicate this. Research provides conflicting evidence of avoidance which can be a difficult symptom to treat or address in trauma populations with exposure demonstrating better effects (Frank, Kosten, Giller & Dan, 1988; Richards, Lovell & Mark, 1994). Indeed, there is literature to suggest that some trauma treatments may exacerbate trauma symptoms (Mott, et al., 2013; Keller, Feeny, & Zoellner, 2014). However post-treatment outcomes are generally found not to be significantly worse than baseline symptoms (Jayawickreme, et al., 2014). Further exploration of whether avoidance might predict symptom exacerbation in treatment has demonstrated that it does not (Larsen, Wiltsey Stirman, Smith & Resick, 2016) and so in the context of this study, there is limited evidence to suggest the higher avoidance scores have impacted the engagement with the CFT intervention. The small non-significant differences on measures on the ANOVAs also support the notion that the higher avoidance scores in the delayed intervention group did not impact the reductions in scores across measures.

Potential explanation relates to the difficulties in measuring and observing significant changes, particularly at the between-group level. There are many

factors which can influence HRV, both on a specific moment-to-moment level and on a more general level. Specifically, actions such as moving in their chair, talking, standing up, changing their rate of breathing, can all influence slight changes in HR and reflective HRV (Nunan, et al., 2010). On a broader level, alcohol and caffeine intake can also influence HRV as well as physical and mental stress (McCraty, Atkinson, Tiller, Rein, & Watkins, 1995; Nunan, et al., 2010). Indeed, it could be reasonably considered that all of the participants were experiencing mental stress given the fact that they were accessing trauma services and willing to engage in an additional intervention whilst awaiting formal trauma-specific therapies.

Additionally, gender and age differences have also been reported for HRV (Migliaro, et al., 2001), specifically that women are often found to have slightly lower baseline HRV than men, and as people age, HRV also lowers (Nunan, et al., 2010). As such the variety of ages and mix of gender in the study participants may lead to difficulties accurately assessing HRV for these groups. For individuals with low HRV, acute reactivity is less (Porges, 2007) and therefore the influence of moving around or talking, may have been less identifiable than those with higher HRV in the first place.

When comparing this information to previous research, some studies primarily focusing on HRV have implemented more strict age-related criteria. For example the inclusion criteria for Rockliff's study (Rockliff et al., 2008) stipulated participants to be aged between 18 and 35 years, therefore allowing for tighter control of age-related HRV differences. Limiting the participants age in this way for the current study would have reduced the number of people able to be recruited given the mean age for the overall sample was 47.10 years. As such, this may be something which could be further investigated in larger scale studies where age could be controlled for in the analysis. Baseline SDNN figures for the sample in the phase two study were lower than those found in the Rockliff et al (2008) sample of healthy adults. In a study by Migliaro and colleagues (2001) they controlled for age and compared samples of 15 to 20 years old participants with those aged 39 to 82 years. They also utilised short

term five-minute HRV recordings and demonstrated that HRV reduces with increasing age. However, it should be noted the two samples were of unequal sizes and the age range for the categorised 'elderly' sample was much broader than the 'young group', which may have also confounded results. Therefore, although the age restrictions, physical stress and breathing pace may influence reductions in HRV, it may also highlight differences between healthy and traumatised samples, in line with literature in this area (Cohen, et al., 1997).

Significant Main Effects

Several measures demonstrated significant improvements over time; DASS-21 Depression, IES-R total, IES-R Avoidance, intrusion and hyperarousal, and FSCRS inadequate-self and hated-self. However, these improvements were independent of immediate or delayed intervention conditions. This may be viewed as promising evidence that engaging in the study did not have any iatrogenic effects in the context of improvements in the anticipated directions. Iatrogenic effects are a common concern amongst psychologists, often defined by increased suicide risk, although there is question as to whether such concerns are necessary (Bryan, et al., 2015). Whilst this study did not capture specific data relating to suicide risk, there had been no related concerns raised and no indication that participants had engaged in any suicidal behaviours. However, this may be worth additional exploration in future studies to add to the literature on iatrogenic effects.

Tentative explanations for the significant main effects of time would allude to participants perceiving or experiencing benefits as a result of being involved in a research study addressing symptoms related to traumatic stress. Positive effects were seen over time on several measures related to traumatic stress, and whether participants received immediate or delayed CFT intervention offered no additional specific benefits. Indeed, looking at the profile plot for the DASS-21 Depression subscale (figure 15), the trend is indicative that the active treatment for each group demonstrated the greatest level of improvement (albeit not reaching statistical significance).

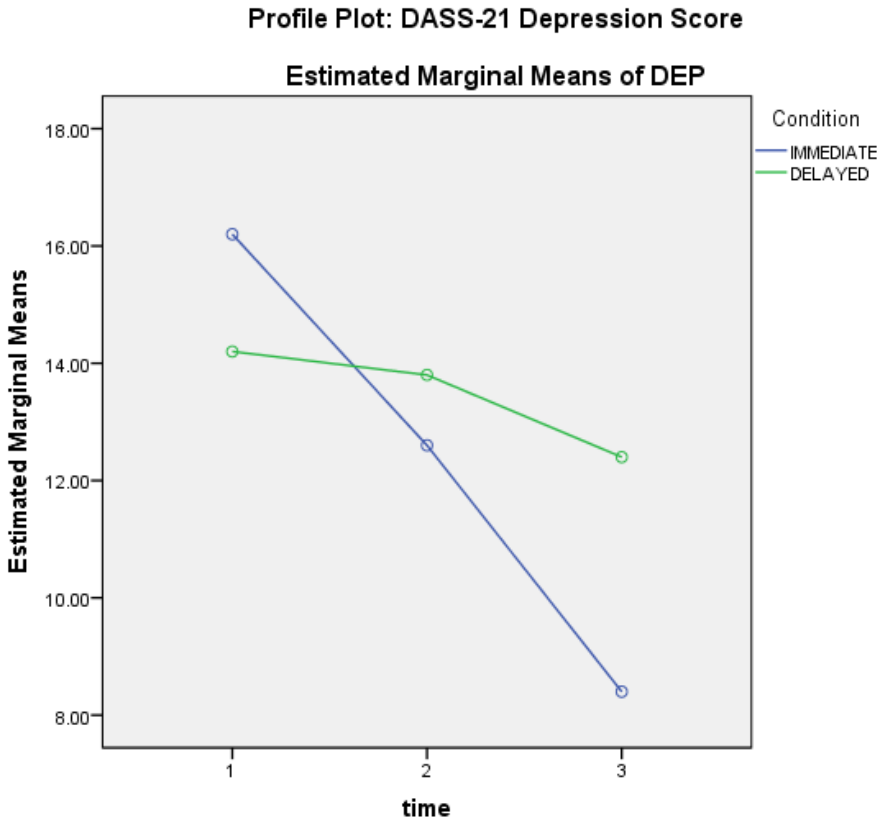

Figure 15. Profile plot of the DASS-21 depression scores

Whilst the small numbers of participants in the current study and the limited significant results, resulted in low observed power, the magnitude of observed effect sizes offers some initial promising insights. . The effects sizes observed on the measures which demonstrated significant main effects can all be interpreted as large (Cohen, 1995; Gray & Kinnear, 2012). Consequently, to find such effect sizes in a small sample indicates scope for further research to explore this in more depth and on a greater scale.

In addition, the confidence intervals around the observed effect sizes indicate the possibility of meaningful change on some of the measures. The DASS-21 total score reduced over time and it has been suggested that a change score of 10.12 is clinically meaningful (Ruwaard, Lange, Schrieken, Dolan & Emmelkamp, 2012). The results for the current study indicate a mean difference score from pre to post intervention of 9.4, with confidence intervals offering a

range of possible effects to indicate meaningful change (CI -.71, 19.51). Unfortunately, there appear to be no reference data for the other measures employed in the study to consider the confidence intervals of the observed effect sizes in the context of clinically meaningful change. Further exploration and studies using these measures, and establishment of clinically meaningful changes would allow richer interpretation of such data.

Contrasts Analyses

As discussed in the results section, the comparison of interest for repeated measures was between pre and post (T_1 and T_3) assessment points, collapsing the two groups. These analyses identified large effect sizes across several measures, notably, depressive symptoms, traumatic stress symptoms (as measured on the IES-R) and self-criticism. Indeed, the effect size found over time in this phase of the study, were less than that found in the first phase, although it remains large. In addition, there were particularly large effects on the IES-R which measures symptoms relating to current traumatic distress relating to a traumatic event. As such, it is posited that the CFT intervention over the brief period demonstrated a substantial impact on traumatic stress. The large effects on self-criticism are also promising given the potential moderating impact this is considered in the literature to have on treatment gains. It is not known how the participants in phase one would have scored on the FSCRS and so it may be that some of the observed differences in effect sizes between the participants in the two phases of the study may be influence by this variable.

Reliable Change Index Analyses

Hypothesis was explored through the application of reliable change indices due to moderation analyses not being conducted on the limited data collected. Considering these individual level analyses offered some insight into this hypothesis.

Self-criticism. Half of the participants achieved reliable change on the inadequate-self subscale of the FSCRS. Based on the clinically significant change cut-off scores, the five participants demonstrated reductions in

inadequate self, bringing their scores in line with the non-clinical population norms. Four out of these five participants could be categorised as high self-critics at the pre-intervention assessment point, based on the cut-off scores provided. On the hated self-subscale, four participants demonstrated reliable change, again with all of these participants demonstrating clinically meaningful change, with scores closer to the non-clinical norms following the intervention.

When taking into consideration these participants' pre-intervention FSCRS scores, these individuals are more highly self-critical. As such, this may indicate promising initial results that the CFT intervention is most beneficial to those who score high on self-critical scales of the FSCRS in comparison to those scoring lowers on these scales from the outset.

Fear of compassion. Over half of the participants demonstrated positive change on the FOC scale, and when exploring these results, four of the participants (Ps 3, 6, 7, and 9) are those who also achieved clinically significant changes on the self-criticism subscales. This offers further support that those who fear self-compassion, and are highly self-critical are likely to see the greatest changes. This also fits with the proposal by Kelly et. al. (2012) that fears of compassion can reduce with practice. Screening of participants reports on their frequency of practice, it is indicated that those participants who demonstrated greatest improvements in these areas reported practising most frequently.

Exploring these outcomes in the context of participants DASS-21 total scores, only two of the participants demonstrated reliable change on this measure. However, Duc, Tran, Tran, & Fisher (2013) suggested a cut off score of 34 on the DASS-21 and when exploring the results, two further participants (P's 6 and 9) fell under this at the post intervention stage, suggesting positive change, not captured by the RCI calculations.

Consideration was given as to whether there may have been any confounding differences in the adherence between groups. However on the data provided by

participants, there was little information to suggest this. In relation to the participants who reported the least frequent intervention practice (Ps 1, 4 and 10), the outcomes on the measures explored in detail above do not suggest a systematic impact of the intervention practice. It could be inferred that one participant (P10) saw the least benefits, although this is not across all of their assessment measures. However their FOC scores increased in line with what can be considered deterioration on the CSC scores. This was also the case with participant (P1). Such results may indicate that those who with poorer adherence to practice see increased fears of self-compassion.

As such, the RCI analyses do not offer evidence to indicate a moderating effect of high self-criticism or fear of compassion on the impact of the CFT intervention on the primary outcome measure. Indeed, further exploration as to other factors influencing the impact of the CFT intervention would be valuable.

Research Strengths

A strength of this research is the acknowledgment of, and acting on, recommendations by McEwan and Gilbert (2016) to explore the use of a brief self-practice CFT intervention with a clinical sample. In addition, phase two of this study has taken that further by exploring this specifically with a trauma population. This is a positive step in the direction of beginning to draw together some of the concepts around the CFT model and exploring them with a trauma population. Due to the increasing use of CFT in trauma therapies (Harman & Lee, 2010), this indicated a current gap in the scientific research of influential factors associated with trauma which may be targeted by compassionate interventions. These factors have not (to the authors knowledge) been studied together in a trauma population.

The attrition rate was also within previously cited levels, demonstrating initial evidence that this intervention and format of measuring change was acceptable to the majority of those who were involved. In addition, the inclusion of measurements of HRV was also acceptable to participants, indicating that future studies would benefit from continuing to implement HRV measures as a

physiological marker in intervention studies for trauma populations. The relatively slow uptake may be an indicator of the high avoidance levels of a trauma population.

The pilot-RCT design offers a way of exploring the effectiveness of the CFT intervention over the waiting list control. Adding data to further power the study would increase the benefit of this design in offering greater ability to interpret the results further.

Research Limitations

There were a number of limitations to the study. Of particular note was the sample size and associated difficulties with power for this phase of the research project. Given that the attrition rate was in line with previous estimates (20% - 48%; Imel, et al., 2013) the initial engagement with the study may be considered. Indeed, of the 38 clients who were assessed and added to the waiting list during recruitment, only 14 demonstrated an interest, with 10 completing the study to date. For those who did engage in the study, the brief nature of the intervention period may have reduced participants' opportunity to benefit from the intervention had they practiced this for a longer period. Although benefits were found over a shorter period previously, it may indicate that a trauma population would benefit from longer, or from additional therapist support.

Participant uptake may have also been impacted by therapists at the trauma service forgetting to highlight the research to clients, thus not obtaining verbal consent for me to contact them further. Alternately, or as well as, those clients who did not demonstrate interest may have formed a subgroup of particularly avoidant, self-critical or anxious individuals who felt unable or unwilling to engage in a waiting list intervention for research purposes. As such, it is not known how representative the current sample is of traumatised individuals. Potentially, offering participants an incentive to engage in the research may have increased uptake, however due to the researchers budget this was not possible.

Another limitation can be related to the study design in that an inherent obstacle for self-practice or self-help interventions is treatment adherence. Being able to accurately establish whether participants are practising the intervention as instructed, and at the level of frequency that they report to researchers is inherently difficult. Given purely self-help interventions are defined by not having any therapist input, no phone calls or contacts were made during the intervention practice periods to offer support or identify if participants were practising. In other designs where more therapist input is an aspect, greater treatment fidelity checks could be carried out. Alternatively, if the audio intervention was made available on an app or a monitored website more detailed monitoring could have occurred. However, not all participants had access to such methods and, due to the pilot nature of this study and financial constraints, an app is not yet available. Whilst participants appeared to be honest during this study, even if this was to highlight that they had been unable to practice for any reasons (for example one participants identified that they had a friend's funeral to attend one day and this impacted on their ability to remember to practice the intervention for two days), capturing proven accuracy data is difficult to do with participants in the community.

The range of traumatic experiences of the study participants may have posed a complicating factor. Previous studies have often focused on populations with similar experience or trauma type, and therefore the heterogeneous sample of participants in this study in relation to their traumatic experiences, coupled with the current low numbers may have impacted on findings. Perhaps future larger scale research investigating specific trauma types could replicate this study in order to facilitate exploration of the CFT intervention for specific trauma populations which may be somewhat more homogenous.

Future Clinical and Research Implications.

Some conclusions can be drawn from phase one of the research project which may inform clinical practice. The general agreement as to the acceptability of the intervention and the feasibility of this being practised by participants suggests that this could be an adjunctive therapeutic intervention for those

accessing community mental health services. This cannot be generalised to all community mental health services but the local services where recruitment took place demonstrated positive acceptance of the self-practice intervention. The large significant effects also demonstrate the potential that the CFT intervention supported participants in reducing symptoms of depression, anxiety and stress. Whilst it cannot be assumed that the CFT intervention accounted for all of these changes, feedback from participants suggested that for some of them, this was the only new thing that had been introduced into their routine and they felt this was directly linked to their subjective experienced of improved symptoms. It offers promising steps to further support for CFT interventions of a brief nature for clients accessing psychological input.

Data collected to date in phase two would benefit from continued recruitment in order to obtain adequate power. This would allow more conclusive interpretation of results. As alluded to previously, this data collection is ongoing with plans for additional data to be collected in relation to follow up. This will be in the form of data from participants following their trauma therapies and would allow the question of whether engaging in a brief CFT intervention while awaiting focused trauma therapies has any impact on outcomes of trauma therapies to be addressed. This would provide scope for further exploration of whether this intervention may provide a helpful adjunct or preparatory phase before commencing focused therapies. Considering the literature about increasing self-compassion and reducing self-criticism as ways to support the enhancement of the emotion regulation systems and reducing the threat system (Gilbert, 2009; Neff, 2003a), this would allow hypotheses to be explored about whether this then promotes better outcomes for trauma therapies.

In addition, further development of models of analysis for additional data collected and future related studies would allow for more rigorous exploration of data collected. This should include intention-to-treat analysis in a larger RCT, to enable further exploration of outcomes, which may also be supported by applying mixed linear modelling. Collection of more detailed attrition information may also inform future study protocols.

With regards to future analyses, it may be beneficial to implement a hierarchy of variables. For the current study, whilst the DASS-21 was identified as the primary outcome measure, the remaining variables were not considered in terms of primacy. Following initial exploratory results, this may be a useful additional step to explore. This may give consideration to differentiating process and outcome variables.

Due to the complexities of the number of influential variables in individual experiences of traumatic stress, future research could seek to explore further insights into the relationships between the variables and implementing different cut-off scores for some of the measures. For example, considering the difficulties previously discussed around the wide use of medical models and diagnostic criteria, and the literature implicating the distress of subclinical PTSD, it may be beneficial to consider exploring varying threshold scores on PTSD symptoms measures. This could be implemented for measures such as the IES-R and the more general measures of distress (i.e. DASS-21) to explore influences that these may have in terms of outcomes following brief CFT practice. Implementing this with larger samples would provide a richer data set to then explore whether there are differing levels of benefit to those with varying levels of symptoms.

Further research to expand on self-practice without therapist contact for CFT interventions could also explore whether having an initial psychoeducational session about the CFT model impacts on individuals' improvements following intervention. Such psychoeducational sessions could be offered in a group format which would enable time-effective use of resources. If further research indicates that such waiting list interventions can enable clients to make the best use of formal therapies, they may require less therapy sessions. This could impact on long waiting times for accessing therapy and therefore more effective service provision (Mind, 2010).

Additional measures relating to therapeutic relationship factors may also provide insights as to whether changes were related to rapport with the

researcher in appointments (Brady, Warnock-Parkes, Barker, & Ehlers, 2015). Although the therapeutic intervention adopted a self-help modality, participants did meet with me on three occasions and whilst the focus was on completing the measures and having their HRV measured, conversations also occurred in relation to how they had found the intervention (for feedback purposes) and they may have experienced positive interpersonal cues in the context of my facial expressions and voice tone which may have enabled them to have a sense of safety in the appointments (Porges, 2003). However, these interactions are further complicated by participants' previous histories, including their traumatic experiences, and their levels of social support from others outside of research appointments (Keller, Zoellner, & Feeny, 2010) and so this is a complicated phenomenon to separate out.

Critical Reflections

This study integrated a number of psychological factors demonstrated to relate to trauma, through evolutionary psychological theory and the compassionate literature. As a result, this has presented challenges in coherently bringing these ideas together from the research where they have sat relatively separately. The factors explored in this research has focused on those which may mediate and/or moderate the maintenance of trauma, which is additional to the large research body already exploring broader risk factors for trauma. However, the benefit of addressing this in the current study has included being able to move the focus away from PTSD specifically and consider traumatic stress as a dimensional experience. The amalgamation of the mediating and moderating factors in this study has not required the specificity of diagnostic PTSD and has been able to consider the experience of traumatic stress from the perspective of theoretical ideas about the threat protection and soothing affiliative systems. From an exploration of Polyvagal theory, prompting interest in the neurophysiological markers related to threat-response and related distress, the emphasis on the assessed factors linked to the evolutionary theory of traumatic stress response and compassion focused research. Finding a way to join these theoretical ideas was the most interesting, as well as challenging, part of this research project from its conception. The relatively recent, and

increasing, interest in the field of compassion focused therapy, its benefits to other psychopathologies, and the increasing recommendations for its application to trauma, meant that it seemed a fitting gap in the literature to try and address.

One of the difficulties was the decision-making process on where to draw a line of which factors to include. There were additional factors which the evolutionary and compassion literature indicated could be associated with trauma symptoms. However, the factors addressed in the final research project were those which had some links made between them in existing literature, which could be tied to trauma and were considered most likely to be able to observe changes in a brief time frame (based on the design of the existing CFT intervention). One factor in particular which had been considered was that of attachment. This was due to my interest in attachment and the large amount of literature in recent years exploring attachment and its relations to the field of trauma and the theoretical links in evolutionary psychology and the compassion literature. However the decision was made not to include measures of attachment for several reasons.

Firstly, in the context of the already considered participant burden of the measures implemented this would have produced an additional requirement on participants. Secondly, exploring early attachments may have offered information about participants' susceptibility to developing trauma, however the primary focus was on trauma maintenance and evaluating the intervention's ability to improve symptoms. Thirdly, attachment styles, particularly in adulthood are thought to be relatively stable (Shallcross, Frazier, & Anders, 2014) although it has also been argued that they are amenable to change through therapeutic endeavours and/or significant experiences (Davila & Cobb, 2004). As such it was concluded that the intervention was unlikely to influence attachment patterns over a short space of time and therefore measuring this was unlikely to offer additional information of clinical use at this stage and it would not be able to be determined whether participants' current attachment styles were influenced by their traumatic experiences (and if so, whether child or adult experiences for those who had multiple traumas).

Reflecting on challenges which arose with this research and difficulties experienced, the main issue related to the limited sample and slow recruitment. This was challenging for several reasons. Firstly, from my perspective of the intervention and my interest in the area, the benefit of practising a compassionate intervention seemed a relatively easy decision to make. Based on feedback given in phase one of the study, and the fact that participants in phase two were waiting for trauma therapy, I overestimated the number of people who would happily engage in the study. On reflection, this is naive given the literature indicating the difficulties experienced of trauma survivors, particularly the avoidant and anxious nature of the distress. However, I perhaps enthusiastically assumed that given all clients had sought therapeutic input through one access point or another (i.e. GP, CPNs etc.) that more of a majority of clients would feel glad to be able to have some form of intervention whilst facing a potentially long wait for formal therapy. However, I quickly learned that this was not the case as recruitment slowed down following an initial interest which thus served a valuable learning point in relation to conducting such research designs. In future research I hope to conduct I will aim to consider alternative or additional ways to support effective recruitment. This may be done with regular meetings with all clinicians. However, this was difficult in the targeted service due to the visiting therapist working different days to one another. Although I believe I have a good awareness of the difficulties of conducting RCTs and the critique of these being gold standard (yet perhaps not always ecologically valid) it still surprised me how difficult recruitment became. However the experience, rather than dishearten me, has provided with me valuable lessons of implementing such a research approach and is something I wish to continue adding to in this area.

Connected to this reflection is the issue that arose regarding phase two being underpowered. Resulting from the small sample and the inadequate power achieved, decisions needed to be made about whether to run the ANOVA analyses. Whilst technically, these analyses would not ordinarily be recommended on a sample of this size, there are very limited options for alternative methods of statistically analysis from a non-parametric perspective

for two-way mixed ANOVAS. As such the decision was made to run them for exploratory purposes with the proviso that data collection for this phase is ongoing. I have certainly been able to enhance my knowledge of statistical research methods through this study, although there were points during the research when the lack of power and the impact this had on the statistics led me to view to data as somewhat obsolete in answering the research aims and hypotheses. Furthermore, phase one demonstrated significantly large effects. Considering the contribution this phase offered by way of extending the McEwan & Gilbert (2016) study provided further data to add to the limited literature for a trauma population. In addition, phase two has taught me not to get disheartened by non-significant results because actually these can tell us a great deal about what is feasible or not and provide direction for whether, and how to explore the area further.

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Appendices

Appendix A: Sample items from each of the measures across phase one and two.

Depression, Anxiety and Stress Scale (DASS-21)
Participants are required to complete the DASS-21 in relation to the past week.

"I found it difficult to relax"
"I felt down-hearted and blue"
I felt I was close to panic"
"I felt like my life was meaningless"

Fears of Compassion (FOC) Scale 3: Expressing kindness and compassion towards yourself.
This subscale focuses on individuals' thoughts and beliefs about self-compassion.

"I feel that I don't deserve to be kind and forgiving to myself"
"If I really think about being kind and gentle with myself it makes me sad"
"Getting on in life is about being tough rather than compassionate"
"When I try and feel kind and warm to myself I just feel kind of empty"

The Forms of Self-Criticising/Attacking & Self-Reassuring Scale (FSCRS)
Participants are asked to rate how true of them each statement is.

"I am easily disappointed with myself"
"I find it difficult to control my anger and frustration at myself"
"I find it easy for forgive myself"
"I feel beaten down by my own self-critical thoughts"

Self-Compassion Scale - Short Form (SCS-SF)
The scale asks participants to consider how they typically act towards themselves in difficult times.

"When I fail at something important to me I become consumed by feelings of inadequacy"
"I'm disapproving and judgemental about my own flaws and inadequacies"
"When something upsets me I try to keep my emotions in balance"
"When I'm feeling down I tend to obsess and fixate on everything that's wrong"

Social Safeness and Pleasure Scale (SSPS)
Participants are asked to rate how they feel in relation to social situations.

"I feel content within my relationships"
"I feel understood by people"
"I feel connected to others"
"I find it easy to feel calmed by people close to me"

Impact of Event Scale-Revised (IES-R)
This scale focuses on one specific event but can be re-administered in relation to different events and over time and the items are rated in relation to the past seven days. Participants were asked to complete this based on the event they feel currently bothers them most.

"I tried to remove it from memory"
"I stayed away from reminders of it"
"I had dreams about it"
"I thought about it when I didn't mean to"

Psychological Well-Being – Post-Traumatic Change Questionnaire (PWB-PTCQ)
Participants are encouraged to think about their feelings about themselves at the *present time* and rate how they have changed as a result of their traumatic experience(s). The items cover six domains, including *self-acceptance, autonomy, purpose in life, relationships, sense of mastery,* and *personal growth.*

"I feel I am in control of my life"
"I respect myself"
"I handle my responsibilities in life well"
"I am grateful to have people in my life who care for me"

Appendix B: Amended CFT intervention script

Compassion Focused Therapy Five Minute Intervention Script

5 minute Compassion Practice

Welcome to this work seeing how a regular focus on oneself as a compassionate person can be helpful to us in our everyday life. How does it work? We don't often think about trying to become a certain kind of person. We might practice playing the piano or football skills but not becoming a certain kind of person. If you think about it, you will notice that most of the time we just feel and act certain ways because of the things that are happening around us. So, for example, if someone annoys us we feel anger and may respond with anger, or if someone makes us anxious we might then respond with being anxious and perhaps submissive. But suppose neither of those responses are really what you want. How could we think about and begin to practice being in the world as a person who we really want to be?

The essence of compassion self-practice is to focus on and imagine the kind of compassionate self we would like to be. Why choose a compassionate self? The reason to focus on compassion is because compassion helps us act in ways that are helpful for our well-being and that of others. Compassion is also a source of enormous courage. For example, imagine you have to go to the hospital for some worrying tests, or you're going through a difficult situation in life, like a divorce. What would you want from your most compassionate friend? Well you would certainly want understanding, kindness and support to help you settle a bit. But you would also want your friend to help you face what you need to face - to give you courage. It wouldn't be very useful if your friend said 'It's all too frightening, just stay at home?'

So compassion is an ability to pay attention to the suffering and difficulties in yourself and others and try to build the courage and wisdom to do what we can to be helpful.

Building your compassionate self

First think about all the qualities you would have if you are at your compassionate best. For example, if a friend was struggling with something, how would you really like to be with them? Or imagine an argument with someone you like. If you are at your calmest compassionate best - how would you deal with this? Make a note of those qualities you see yourself enacting.

They could include patience, strength, friendliness, confidence and wisdom. Basically in a moment, we are going to simply practice imagining having those key qualities and how we would act when we were in a compassionate state of mind.

Take a few moments to make yourself a list, and then work through the following exercises, pausing where you need to and give yourself time. Once you have worked through them a few times, you might find them easier to do, and need less time to pause in between exercises.

Here are the exercises

1. Soothing rhythm breathing - 45 seconds
We can help to create a compassionate sense of self by paying attention to our body and in particular our breathing. If we slightly deepen and slow the breath we might notice a sense of slowing down inside. This might come with a feeling of the body becoming slightly heavier. If we speed up our breathing, we are more likely to feel a bit lightheaded.

Sitting or standing comfortably, allow air to go in through your nose and down into your diaphragm. Then after a short pause let it come out naturally, again through your nose. Try not to force it out but just allow it to come out naturally and easily. So nice smooth breaths in and out – this might take a bit of practice.

Now, breathe slightly slower and deeper than you would normally. This is called soothing rhythm breathing. While you can find a pace for breathing that you're comfortable with, you can try counting from 1 to 4 or 5 (a second at a time). Do this for the in-breath, hold for a short pause and then allow the breath to come out again through the nose on a count of about 1 to 4 or 5. Find what feels comfortable for you.

Once you have the hang of it, you don't need to count unless it helps you, but you are aiming for about 5-6 breaths per minute. So try this for about 45 seconds. The key thing to notice is the sense of slowing down inside and your body becoming a little heavier. It can sometimes help to place your right hand on your heart and think about feeling the breaths smoothly and deeply into this area.

2. Say 'Hello' to yourself – 15 seconds neutral, 15 seconds friendly
Next keep doing this soothing breathing but now focus on creating a friendly facial expression and a friendly voice tone too. You may find it helpful to see yourself in front of a mirror, if you are comfortable with this. Instead, you may wish to focus on the sensations of your facial expression and voice tone. Either is fine.

On the out breath, say hello to yourself. Say "hello" followed by your first name. First, try a neutral way. Focus first on the out-breath with a neutral facial expression and voice tone - say hello to yourself for the next 15 seconds.

And now try a friendly way – as if you are talking to someone you care about. Then have 15 seconds of creating a gentle, friendly facial expression and friendly voice to say hello to yourself.

Take a moment to see what you can notice. Sometimes we notice that creating a friendly voice tone offers a slight change of feeling. Having friendly textures to our thoughts stimulates systems in our brain that are helpful for well-being. If we create hostile textures to thoughts or become self-judgemental, this is not helpful to our well-being and can contribute to feeling anxious or depressed.

Each time you find yourself hearing self-critical thoughts or judgments, take a few deep breaths and try and refocus on friendly thoughts and saying hello to yourself in a friendly way.

3. Imagine having ideal compassionate qualities – 45 seconds
The next exercise is to continue the soothing breathing and friendly facial expressions and voice tones, whilst imagining yourself at your compassionate best. So keep your soothing rhythm breathing and begin to imagine yourself having your ideal compassionate qualities. You may wish to use your list that you created at the beginning. These qualities could be patience, confidence, courage, wisdom, caring, strength or others. Try to recognise and focus on three particular qualities that are meaningful to you. Spend 45 seconds with a friendly facial expression and imagine being in the world with these qualities – How are you acting? How do others react to you? Make a commitment to try to be helpful when things are difficult either for you or for others.

4. Focusing compassion on others – 1 minute
Now this really gets going when we focus on it. So for the next minute, bring someone to mind who you care about and on the out breath focus on the wish for them to find peace and be happy. You can say in your mind 'May you find peace', 'May you be happy' and name that person. As you do this, try to create that friendly voice tone and facial expression. Do that for one minute and see what happens.

Notice how that made you feel.

Now we are going to focus your compassionate self on you. Sometimes people find this more difficult, so don't worry if you do, just see how far you get.

5. Focusing compassion on self – 1 minute
Keeping your soothing rhythm breathing and your compassionate voice tone and facial expression, imagine you can see yourself in your mind's eye and focus on the idea of: 'May you find peace; may you be happy'. Sometimes people like to think of it as may 'I' find peace, may I be happy. Do whichever makes you feel most comfortable. Others like to focus on naming themselves. Remember to also focus on the pleasure you would get if this could be true.

Some people commonly note some resistance to this, as if they're not entitled to compassion – which is sad really because compassion is a way of building strengths. But if that's true for you don't worry. Just focus on the idea 'May I be compassionate to that which resists compassion.

Each time you find yourself hearing self-critical thoughts or judgments, take a few deep breaths and try and refocus on friendly thoughts. Repeat the words 'May you find peace; may you be happy' in your best compassionate way.

So for the next one minute, spend some time keeping yourself in your mind's eye, focusing on the idea may I find peace, may I be happy.

6. Focusing compassion on challenges – 1 minute
Next think of a situation that is slightly difficult for you -- nothing too hard to begin with. Please do not focus on traumatic events you may have experienced. Choose a mild difficulty or minor stressful situation for this exercise. Spend a few moments thinking of a situation you can focus on.

Move into the compassionate self with all those qualities that you have imagined and a real intent to become a confident, compassionate person who brings wisdom, strength and commitment to situations. Imagine how you, as this most compassionate person, want to deal with this challenging situation. See if any new insights or ideas come to mind. Spend one minute focusing compassion on this difficulty.

Sometimes it can be helpful to write about situations that are bothering us but through the eyes of a compassionate other. This may be something you want to do separately.

Keep going

Continue to try putting yourself into a compassionate space where you practice slowing your breath, creating a compassionate voice tone and allowing yourself to feel what it might be like to be this most compassionate person. Even after you have finished practice just allow yourself to continue walking around and holding on to that sense of being a compassionate self.

Each time you find yourself hearing self-critical thoughts or judgments, take a few deep breaths and try and refocus on friendly thoughts. Repeat the words 'May I find peace; may I be happy' in your best compassionate way.

As you practice you may notice that perhaps you want to do more compassionate things, even small things like take more of an interest in others or say hello in a more friendly way. Notice if you are someone who tends to be critical of yourself or gets easily disappointed and frustrated. These emotions are very easy to stimulate within us but are not helpful. Try to notice when they arise and switch to a 'compassionate voice'. This is not letting yourself off the hook in anyway because compassion will always face the issues - it is just doing it in a way that is helpful. So one trick is to always notice how you talk to yourself and use your ability to create a friendly voice in your head. Try not to speak to yourself in a tone or way that you wouldn't want to use to talk to a friend.

Your five-minute practice

1. Soothing rhythm breathing - 45 seconds

2. Say 'Hello' to yourself – 15 seconds neutral, 15 seconds friendly

3. Imagine having ideal compassionate qualities – 45 seconds

4. Focusing compassion on others – 1 minute

5. Focusing compassion on self – 1 minute

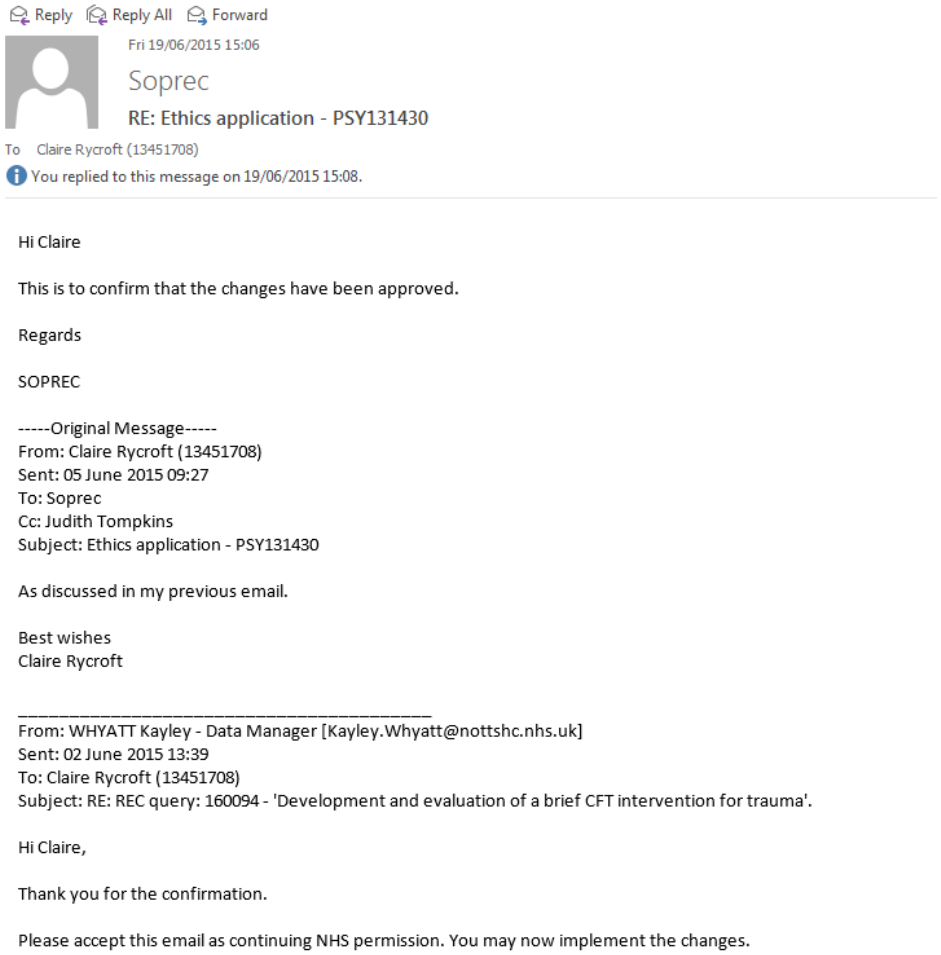
6. Focusing compassion on little challenges – 1 minute

If you wish to spend longer on this practice, please do so. It may be helpful to spend extra time on practicing compassion for yourself and small challenges

you may be facing. It is important that you do not use these exercises to focus on traumatic events, as these will be explored with support from your therapist once you begin formal therapy.

Appendix C: Ethical Approval.

School of Psychology Research Ethics Committee (SOPREC) correspondence (in order of most recent approval first).



Reply Reply All Forward

Fri 19/06/2015 15:06

Soprec

RE: Ethics application - PSY131430

To Claire Rycroft (13451708)

You replied to this message on 19/06/2015 15:08.

Hi Claire

This is to confirm that the changes have been approved.

Regards

SOPREC

-----Original Message-----
From: Claire Rycroft (13451708)
Sent: 05 June 2015 09:27
To: Soprec
Cc: Judith Tompkins
Subject: Ethics application - PSY131430

As discussed in my previous email.

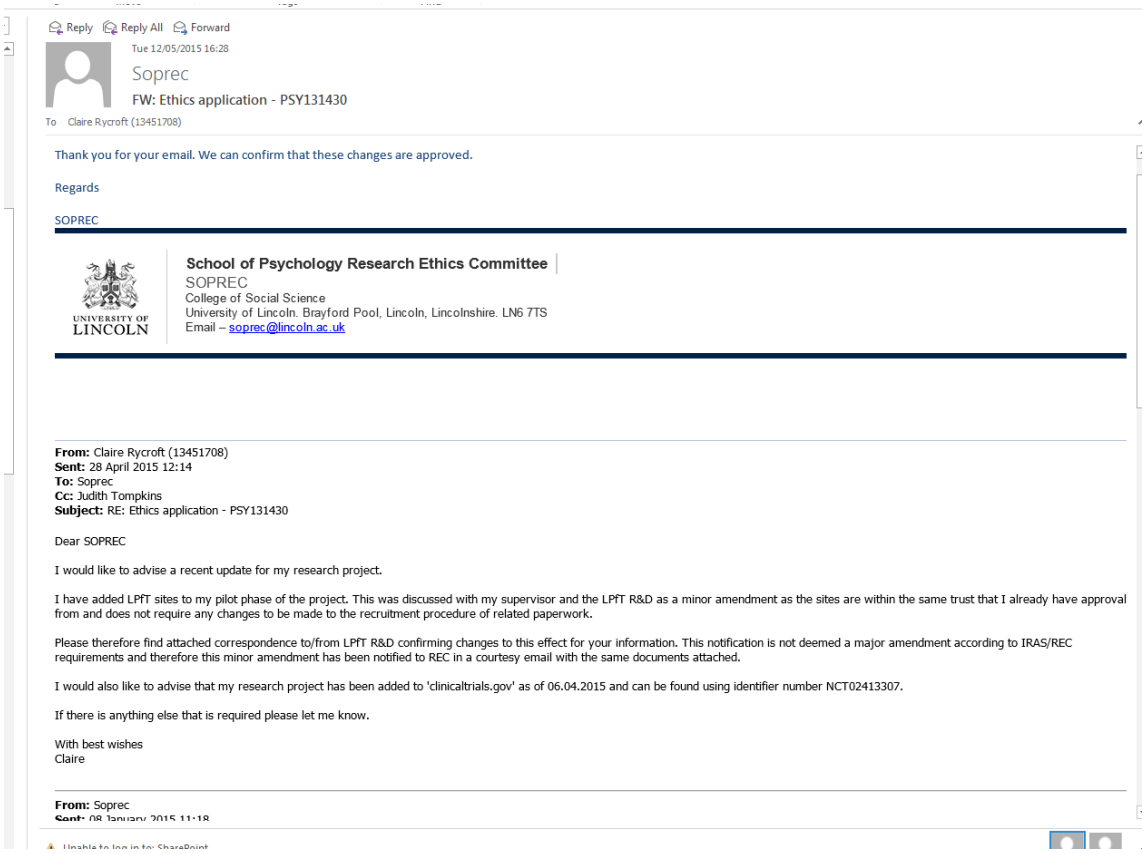
Best wishes
Claire Rycroft

_____
From: WHYATT Kayley - Data Manager [Kayley.Whyatt@nottshc.nhs.uk]
Sent: 02 June 2015 13:39
To: Claire Rycroft (13451708)
Subject: RE: REC query: 160094 - 'Development and evaluation of a brief CFT intervention for trauma'.

Hi Claire,

Thank you for the confirmation.

Please accept this email as continuing NHS permission. You may now implement the changes.



Reply Reply All Forward

Tue 12/05/2015 16:28

Soprec

FW: Ethics application - PSY131430

To Claire Rycroft (13451708)

Thank you for your email. We can confirm that these changes are approved.

Regards

SOPREC

UNIVERSITY OF LINCOLN

School of Psychology Research Ethics Committee
SOPREC
College of Social Science
University of Lincoln. Brayford Pool, Lincoln, Lincolnshire. LN6 7TS
Email – soprec@lincoln.ac.uk

From: Claire Rycroft (13451708)
Sent: 28 April 2015 12:14
To: Soprec
Cc: Judith Tompkins
Subject: RE: Ethics application - PSY131430

Dear SOPREC

I would like to advise a recent update for my research project.

I have added LPfT sites to my pilot phase of the project. This was discussed with my supervisor and the LPfT R&D as a minor amendment as the sites are within the same trust that I already have approval from and does not require any changes to be made to the recruitment procedure of related paperwork.

Please therefore find attached correspondence to/from LPfT R&D confirming changes to this effect for your information. This notification is not deemed a major amendment according to IRAS/REC requirements and therefore this minor amendment has been notified to REC in a courtesy email with the same documents attached.

I would also like to advise that my research project has been added to 'clinicaltrials.gov' as of 06.04.2015 and can be found using identifier number NCT02413307.

If there is anything else that is required please let me know.

With best wishes
Claire

From: Soprec
Sent: 08 January 2015 11:18

Unable to log in to: SharePoint

Reply Reply All Forward

Thu 08/01/2015 11:19

Soprec

FW: Ethics application - PSY131430

To Claire Rycroft (13451708)

Cc Judith Tompkins

You replied to this message on 28/04/2015 12:14.

Message | Consent Form - Stage One V2.docx (24 KB) | Participant Information Sheet - Stage One V2.docx (25 KB) | Participant Information Sheet - Stage Two v3.docx (24 KB) | Compassion Focused Therapy intervention.docx (27 KB) | 14-WA-1213 FavOp.pdf (216 KB)

Dear Claire

Thank you for this update. We can confirm that your ethical approval application has now been considered and approved.

Regards

SOPREC

UNIVERSITY OF LINCOLN

School of Psychology Research Ethics Committee
SOPREC
College of Social Science
University of Lincoln. Brayford Pool, Lincoln, Lincolnshire. LN6 7TS
Email – soprec@lincoln.ac.uk

From: Claire Rycroft (13451708)
Sent: 16 December 2014 09:06
To: Soprec
Cc: Judith Tompkins
Subject: RE: Ethics application - PSY131430

Dear SOPREC

I have now received ethical approval from IRAS for my research project. I have also addressed the points raised by SOPREC (below).

Please find attached a copy of the relevant documents with amendements and the favourable opinion from IRAS (REC).

Best wishes
Claire

From: Soprec
Sent: 28 July 2014 13:04

Reply Reply All Forward

Mon 28/07/2014 13:04

Soprec

Ethics application - PSY131430

To Claire Rycroft (13451708)

Cc Judith Tompkins

You replied to this message on 16/12/2014 09:06.

Dear Claire

Your ethical approval was considered at our recent SOPREC meeting. The committee would like confirmation if this application has already been submitted and approved by the Nottinghamshire Healthcare Trust? If this has been approved by the Trust, please can you email the evidence to soprec@lincoln.ac.uk

If this has not been approved by the Nottinghamshire Healthcare Trust, then the Committee will provisionally approve, subject to the following amendments being made and emailed to soprec@lincoln.ac.uk :

- More focus on the intervention tasks
- Wording in the information sheet should be checked
- Contacted details of SOPREC to be included, in case people wish to raise any complaints
- An information sheet/consent form should be included for the Lincoln subset

Kind regards

UNIVERSITY OF LINCOLN

School of Psychology Research Ethics Committee
SOPREC
College of Social Science
University of Lincoln. Brayford Pool, Lincoln, Lincolnshire. LN6 7TS
Email – soprec@lincoln.ac.uk

EA2

Ethical Approval Form:

Please word-process this form, handwritten applications will not be accepted

UNIVERSITY OF LINCOLN

This form must be completed for each piece of research activity whether conducted by academic staff, research staff, graduate students or undergraduates. The completed form must be approved by the designated authority within the College.

Please complete all sections. If a section is not applicable, write N/A.

1 Name of Applicant	Claire Rycroft	
	School: Psychology	College: Social Sciences
2 Position in the University	Student	
3 Role in relation to this research	Primary Researcher	
4 Brief statement of main Research Question	The aims of the project are to develop a five-minute Compassion Focused Therapy (CFT) intervention, suitable for self-practice for trauma clients and to investigate the potential benefits as a precursor to Treatment as Usual (TAU). *Hypotheses:* i. A brief CFT intervention will decrease levels of depression, anxiety, stress and increase baseline Heart Rate Variability. ii. CFT will increase experiences of self-compassion, social safeness, and reduce levels of self-criticism. iii. High 'fear of compassion' will moderate the impact of CFT and result in smaller changes in depression, anxiety, stress and posttraumatic change.	
5 Brief Description of Project	The project will involve adapting and implementing a five-minute daily self-practice CFT intervention and evaluate its impact on psychological and physiological factors associated with trauma. It aims to offer a novel intervention which may facilitate further benefits from trauma-specific therapy. Follow-up data may demonstrate the maintenance of positive effects as well as increased positive effects if self-practice is continued. This would be a unique use of self-practice CFT specifically for trauma clients.	

The study will use a controlled clinical trial, waiting-list cross-over block design with clients referred to the Centre for Trauma, Resilience and Growth (CTRG). Participants will engage in a daily five-minute self-practice CFT intervention prior to engaging in trauma-specific therapy. The CFT intervention will be adapted specifically for trauma clients based on the literature review, involvement of service users, and close collaboration with Paul Gilbert.

The current version of the CFT intervention includes instructions, an explanation of compassion and several exercises designed to increase self-compassion (e.g. breathing exercises and compassionate imagery exercises focused on self and others). Adaptation will include explicit instructions not to focus on traumatic events participants may have experienced. This will be addressed in their trauma-specific therapy at the CTRG. Participants will be encouraged to focus on milder difficulties and stressors. The adaptations will account for the current literature in CFT and maintain its basic principles. The focus will remain on building self-compassion and reducing self-criticism.

The project will involve three stages, outlined below;

Stage 1: The sample for this stage will be sought from the Community Forensic Team in Lincolnshire (NHS LPfT) where the primary researcher is based on placement. Many clients accessing this service have previous experience of traumatic events and experience symptoms of depression, anxiety and stress. Participants will be offered the opportunity to use the CFT intervention alongside therapy they are already receiving and will be asked to provide qualitative feedback on the ease of use, clarity of instructions, and perceived benefits of the intervention. Any comments or concerns will be considered in making amendments to the final version of the intervention. Members of the Service User and Carer's Advisory Panel (SUCAP) will also be invited to be involved in this stage of the project and have demonstrated a keen interest in this.

The sample size for this stage is not explicitly defined and will depend on the number of interested parties. This aims to test feasibility and acceptability of the intervention and its instructions with a clinical population. Participants must be able to understand verbal and written instructions in English to be able to engage in the process and to avoid difficulties associated with translating the intervention at this stage.

Stage 2: The research will utilise a single-blind blocked-randomisation design, incorporating three-week intervention versus waiting-list blocks. Following the end of the initial block, participants will then cross over to the alternative condition. Both routine and project-specific outcomes measures will be implemented.

Therapists from the CTRG will conduct routine screening assessments and post trauma therapy assessments. All other measurements will be completed with the primary researcher. Prospective participants will be provided with an information sheet (Appendix A) as part of the screening interview and, if they consent, will be contacted by the researcher. They will be given the opportunity to ask questions and be asked to sign a consent form if they wish to participate (Appendix B). An initial appointment will then be made and the pre-intervention assessments completed. Participants will be allocated to the CFT or waiting-list condition using blocked randomisation (Saghaei, 2004). Participants will be allocated using a one-to-one ratio with block sizes of four and two using approved web-based software (Urbaniak & Plous, 1997).

Self-report measures will be uploaded to an academically-focused online survey tool (Bristol online survey) and participants will have Heart Rate Variability measurements taken during face-to-face appointments with the primary researcher. A description of all measures can be found in Appendix C.

The five-minute CFT self-practice intervention will be available both in written and audio (CD and mp3) formats. It will be accessible online using a personal login generated by participants for those who have internet access. Participants will receive a daily email or text reminder to

practice the intervention if chosen by them. Participants will be given the choice to complete a daily monitoring sheet (Appendix D) or have their daily online access monitored to record levels of CFT practice. Participants will be asked to practice the intervention on a daily basis for three weeks with repeated completion of the online assessments and the Heart Rate Variability measurements in the week following the block.

The sample was calculated using G*Power 3.1.9 software (Faul, Erdfelder, Buchner & Lang, 2009). With the Depression, Anxiety and Stress Scale (DASS-21: Lovibond & Lovibond, 1995) as the primary outcome measure, the average effect size of the relationship between CFT and mental health symptoms was equivalent to a large effect size *f* of .64 (MacBeth & Gumley, 2012). An average estimate of test-retest reliability is 0.77 (Brown, Chorpita, Korotitsch & Barlow, 1997). Given the number of groups (2) and repetitions (3) in the planned study, a sample size of at least 20 (10 per group) will be required to provide sufficient power (80%) to detect an effect of similar magnitude (*f* = .64) at an alpha level of .05.

Due to attrition rates for clients with PTSD and the fact that the CFT intervention is in addition to participants' usual involvement with the CTRG, a cautious attrition rate of approximately 50% was considered and therefore a sample size of 40 participants will be recruited in total. Given the 150 referrals received by the CTRG last year, this appears feasible. Participants will be may be male or female and must be over the age of 18 years.

The main objectives of the project can be analysed using a 2 x 3 ANOVA, with time (baseline, post CFT, post TAU) as a within-subject factor and group (CFT vs. waiting list) as the between-subjects factor. The DASS-21 (Lovibond & Lovibond, 1995) is the primary outcome measure.

Participants will be eligible to take part in the project if they meet the following criteria:

- They are able to understand verbal and written English language (due to resources, the adapted intervention will not be translated);
- They have been accepted onto the CTRG's waiting list;
- Able to access a computer, CD player or mp3 file.

Participants involved in Stage One of the project will be excluded in order to protect against biases from involvement in the development stage. Participants with learning or communication difficulties will also be excluded from this project due to adapted versions of the intervention not yet being available.

Stage 3: All participants will be invited to complete follow-up assessments following the end of trauma-specific therapy. Participants will also be able to offer qualitative information about their continued or discontinued practice of the CFT intervention and their experiences (Appendix E). CTRG therapists will be approached for descriptive data about their therapeutic orientation, therapy content and number of sessions provided in TAU engaged in by project participants (Appendix F). This data can be used to contextualise other potential influences on the outcome data.

Potential secondary analyses regarding the correlation between the main and additional outcome measures will be considered. If follow-up measurements are available, data may be analysed using Multi-Level Modelling, with the DASS and IES as target variables, and the additional measures as predictor variables.

Approximate Start Date:	Approximate End Date:
October 2014	October 2015

<table>
<tr><td rowspan="2">6 Name of Principal Investigator or Supervisor</td><td colspan="2">Primary Supervisor

Dr. Thomas Schroder</td></tr>
<tr><td>Email address:

thomas.schroder@nottingham.ac.uk</td><td>Telephone:

0115 846 6646</td></tr>
<tr><td>7 Names of other researchers or student investigators involved</td><td colspan="2">1. Dr. Rachel Sabin-Farrell (Secondary Supervisor)</td></tr>
<tr><td>8 Location(s) at which project is to be carried out</td><td colspan="2">Stage One: Lincolnshire Partnership Foundation Trust (LPFT) Community Forensic Team, Carholme Court, Long Leys Road, Lincoln, LN1 1FS

Stages Two and Three: Centre for Trauma, Resilience and Growth, St Ann’s House, 114 Thorneywood Mount, Nottingham NG3 2PZ.</td></tr>
</table>

NHS Research Ethics Committee (in order of most recent approval first).

Part of the research infrastructure for Wales funded by the National Institute for Social Care and Health Research, Welsh Government
Yn rhan o seilwaith ymchwil Cymru a ariannir gan y Sefydliad Cenedlaethol ar gyfer Ymchwil Gofal Cymdeithasol ac Iechyd, Llywodraeth Cymru

NISCHR
Gwasanaeth Moeseg Ymchwil | RES | Research Ethics Service

North Wales REC (Central & East)
G1/G2 Croesnewydd Hall
Croesnewydd Road
Wrexham Technology Park
Wrexham LL13 7YP

Telephone : 01978 726377

E-mail : tracy.biggs@wales.nhs.uk

Website : www.nres.nhs.uk

11December 2014

Miss Claire Rycroft
Trainee Clinical Psychologist
Lincolnshire Partnership Foundation Trust (LPFT)
College of Social Science, University of Lincoln
Bridge House, Brayford Pool
LN6 7TS

Dear Miss Rycroft

Study title:	**The development and evaluation of a brief Self-Practice Compassion-Focused Therapy (CFT) intervention as a precursor to TAU for trauma patients.**
REC reference:	**14/WA/1213**
IRAS project ID:	**160094**

Thank you for your letter of 13 November 2014, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information was considered by a Sub-Committee of the REC at a meeting held on 05 December 2014. A list of the Sub-Committee members is attached.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager, Mrs Tracy Biggs, Tracy.Biggs@Wales.nhs.uk. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation

Sponsors are not required to notify the Committee of approvals from host organisations

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.
There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from NRES. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS sites

The Committee has not yet completed any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. We will write to you again as soon as an SSA application(s) has been reviewed. In the meantime no study procedures should be initiated at non-NHS sites.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Confirmation of Professional Indemnity 1Aug14-31July15.pdf]		29 July 2014
GP/consultant information sheets or letters [GP Letter Stage Two V1 docx.docx]	1.0	13 November 2014
Interview schedules or topic guides for participants [Compassion Focused Therapy intervention]	2.0	29 August 2014
IRAS Checklist XML [Checklist_27102014]		27 October 2014
IRAS Checklist XML [Checklist_24112014]		24 November 2014

Non-validated questionnaire [Participant Monitoring Sheet - Stage Two]	1.0	23 July 2014
Non-validated questionnaire [Patient Feedback - Stage One]	1.0	29 August 2014
Non-validated questionnaire [Patient Follow up questionnaire - Stage Two]	2.0	29 August 2014
Non-validated questionnaire [Therapist Feedback Questionnaire - Stage Two]	1.0	29 August 2014
Other [REC opinion response.docx]	1.0	13 November 2014
Participant consent form [Consent Form - Stage Two]	3.0	13 November 2014
Participant consent form [Stage One]	2.0	13 November 2014
Participant information sheet (PIS) [Stage Two]	3.0	13 November 2014
Participant information sheet (PIS) [Stage One]	2.0	13 November 2014
REC Application Form [REC_Form_24102014]		24 October 2014
Research protocol or project proposal [Full Research Project Proposal V3]	3.0	10 October 2014
Summary CV for Chief Investigator (CI/Student) - CV Claire Rycroft IRAS 19.10.14]	1.0	19 October 2014
Summary CV for supervisor (student research) [Academic Supervisor- Rachel Sabin Farrell	1.0	30 October 2014
Summary CV for supervisor (student research) [Academic Supervisor- CV Thomas Schroder 130218.doc]		17 February 2013
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Flowchart of Stage Two processes]	3.0	10 October 2014
Validated questionnaire [Social safeness and pleasure scale.doc]		
Validated questionnaire [Short Self Compassion Scale.pdf]		10 October 2014
Validated questionnaire [Depression Anxiety and Stress Scale Short.doc]		
Validated questionnaire [Forms of self-criticising and self reassuring scale.pdf]		
Validated questionnaire [Fear of Compassion Scale]		
Validated questionnaire [Psychological Well Being-Post Traumatic Change Questionnaire Clients version]		
Validated questionnaire [Impact of Events Scale Revised]		

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

Notifying substantial amendments
Adding new sites and investigators
Notification of serious breaches of the protocol
Progress and safety reports
Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

14/WA/1213	Please quote this number on all correspondence

With the Committee's best wishes for the success of this project.

Yours sincerely

T.A. Biggs.

Professor Alex Carson
Chair

E-mail: tracy.biggs@wales.nhs.uk

Enclosures: *List of names and professions of members who were present at the meeting and those who submitted written comments*

"After ethical review – guidance for researchers"

Copy to: *Sponsor contact - Dr Thomas Schroder*

Lead NHS R&D contact - Miss Emma Pearson, Nottinghamshire Healthcare NHS (Centre for Trauma, Resilience and Growth

Wales REC 4

Attendance at Sub-Committee of the REC meeting on 05 December 2014

Committee Members:

Name	*Profession*	*Present*	*Notes*
Professor Alex Carson - Chair	Retired	Yes	
Dr Kath Clarke	Deputy Associate Chief of Staff, Nursing	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Mrs Tracy Biggs	Research Ethics Committee Manager

Styles
Croesnewydd Road
Wrexham Technology Park
Wrexham LL13 7YP

Telephone: 01978 726377

E-mail: tracy.biggs@wales.nhs.uk

Website : www.nres.nhs.uk

Gwasanaeth Moeseg Ymchwil | **RES** | Research Ethics Service

12 November 2014

Miss Claire Rycroft
Trainee Clinical Psychologist
Lincolnshire Partnership Foundation Trust (LPfT)
College of Social Science, University of Lincoln
Bridge House, Brayford Pool
LN6 7TS

Dear Miss Rycroft

Study Title:	**The development and evaluation of a brief Self-Practice Compassion-Focused Therapy (CFT) intervention as a precursor to TAU for trauma patients.**
REC reference:	**14/WA/1213**
IRAS project ID:	**160094**

The Research Ethics Committee reviewed the above application at the meeting held on 05 November 2014. Thank you for being available on the telephone to discuss the application.

Provisional opinion

The Committee is unable to give an ethical opinion on the basis of the information and documentation received so far. Before confirming its opinion, the Committee requests that you provide the further information set out below.

Authority to consider your response and to confirm the Committee's final opinion has been delegated to a meeting of the Sub committee of the REC.

Further information or clarification required

i. Study design and methodology to be revised to include a control group.

ii. Clarification of the safeguarding procedure in place in the event of distress ensuring that the mechanism is robust.

iii. Participant Information Sheet must be explicit whether participants will be randomised or not and should be amended accordingly to account for the revised methodology.

iv. Participant Information Sheet to include a clear support mechanism in the event of distress.

v. Participant Information Sheet – Invitation paragraph should indicate that the study is being undertaken as an educational project. 'Who has reviewed this study?' Wales REC 4 should be identified as the REC reviewing body.

vi GP letter to be provided. Participant Information sheet and consent form to be revised to include notification that you intend to inform the GP and the option to consent thereto.

If you would find it helpful to discuss any of the matters raised above or seek further clarification from a member of the Committee, you are welcome to contact the REC Manager in the first instance.

When submitting a response to the Committee, the requested information should be electronically submitted from IRAS. A step-by-step guide on submitting your response to the REC provisional opinion is available on the HRA website using the following link: http://www.hra.nhs.uk/nhs-research-ethics-committee-rec-submitting-response-provisional-opinion/

Please submit revised documentation where appropriate underlining or otherwise highlighting the changes which have been made and giving revised version numbers and dates. You do not have to make any changes to the REC application form unless you have been specifically requested to do so by the REC.

The Committee will confirm the final ethical opinion within a maximum of 60 days from the date of initial receipt of the application, excluding the time taken by you to respond fully to the above points. A response should be submitted by no later than 12 December 2014.

Summary of the discussion at the meeting

Social or scientific value; scientific design and conduct of the study

The Committee agreed that the protocol may not answer the research question as this is an untried therapy and potentially damaging or detrimental as there is no adequate control group.

Favourable risk benefit ratio; anticipated benefit/risks for research participants (present and future)

Clarification of what distress mechanism will be in place following further discussions with the team is required.

Care and protection of research participants; respect for potential and enrolled participants' welfare and dignity

A more robust distress mechanism to be provided when finalised.

Informed consent process and the adequacy and completeness of participant information

Participant information to be amended accordingly following the study methodology and design revision.

Suitability of the applicant and supporting staff

The Committee received and noted Academic Supervisor Dr Sabin-Farrell's CV

Suitability of supporting information

The Committee noted that it is the intention to inform the GP of involvement. However, a GP letter was not submitted and there was no reference to this in the PIS and the option to consent to the GP being informed had been omitted from the Consent Form.

Documents reviewed*

The documents reviewed at the meeting were:

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Confirmation of Professional Indemnity 1Aug14-31July15.pdf]		29 July 2014
Interview schedules or topic guides for participants [Compassion Focused Therapy intervention]	2.0	29 August 2014
IRAS Checklist XML [Checklist_27102014]		27 October 2014
Non-validated questionnaire [Participant Monitoring Sheet - Stage Two]	1.0	23 July 2014
Non-validated questionnaire [Therapist Feedback Questionnaire - Stage Two]	1.0	29 August 2014
Non-validated questionnaire [Patient Follow up questionnaire - Stage Two]	2.0	29 August 2014
Non-validated questionnaire [Patient Feedback - Stage One]	1.0	29 August 2014
Participant consent form [Consent Form -Stage One]	1.0	29 August 2014
Participant consent form [Consent Form -Stage Two]	2.0	23 July 2014
Participant information sheet (PIS) [Participant Information Sheet-Stage One]	1.0	10 October 2014
Participant information sheet (PIS) [Participant Information Sheet-Stage Two] *	2.0	10 October 2014 *
REC Application Form [REC_Form_24102014]		24 October 2014
Research protocol or project proposal [Full Research Project Proposal V3]	3.0	10 October 2014
Summary CV for Chief Investigator (CI) [Chief Investigator- CV Claire Rycroft IRAS 19.10.14]	1.0	19 October 2014
Summary CV for student [Chief Investigator- CV Claire Rycroft IRAS 26.09.14.doc]	1.0	19 October 2014
Summary CV for supervisor (student research) [Academic Supervisor- CV Thomas Schroder 130218.doc]		17 February 2013
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Flowchart of Stage Two processes]	3.0	10 October 2014
Validated questionnaire [Forms of self-criticising and self reassuring scale.pdf]		
Validated questionnaire [Impact of Events Scale Revised]		
Validated questionnaire [Short Self Compassion Scale.pdf]		10 October 2014
Validated questionnaire [Fear of Compassion Scale]		
Validated questionnaire [Social safeness and pleasure scale.doc]		
Validated questionnaire [Depression Anxiety and Stress Scale Short.doc]		
Validated questionnaire [Psychological Well Being-Post Traumatic Change Questionnaire Clients version]		
Summary CV for supervisor (student research) Dr Rachel Sabin-Farrell		30 October 2014

*Please note that the version number and date has been taken from the document and not the checklist.

Membership of the Committee

The members of the Committee who were present at the meeting are listed on the attached sheet

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

Yours sincerely

Professor Alex Carson
Chair

E-mail: tracy.biqqs@wales.nhs.uk

Enclosures: *List of names and professions of members who were present at the meeting and those who submitted written comments.*

Copy to: *Sponsor contact - Dr Thomas Schroder*

Lead NHS R&D contact- Miss *Emma Pearson, Nottinghamshire Healthcare NHS (Centre for Trauma, Resilience and Growth*

Wales REC 4
Attendance at Committee meeting on 05 November 2014

Committee Members:

Name	*Profession*	*Present*	*Notes*
Mrs Celia Blomeley	Retired Assistant Headteacher	Yes	
Professor Alex Carson - Chair	Retired	Yes	
Dr Kath Clarke	Deputy Associate Chief of Staff, Nursing	No	
Dr John Clifford	Consultant Psychiatrist	Yes	
Dr John Delieu	Anatomist & DI for HTA Licence	Yes	
Mr John Gittins	Coroner	No	
Mrs Yvonne Harding	Associate Chief of Staff (Nursing) Children & Young People	Yes	
Miss Joy Hickman	Consultant Orthodontist	No	
Dr Peter Hobson	Principal Healthcare Scientist (Research)	No	
Ms Alison Ledward	Former Midwife/Current Researcher	Yes	
Mr Philip Richards	Associate Specialist - Surgery	Yes	
Dr David Southern	Consultant Anaesthetist	Yes	
Ms Eunice Vincent	Retired Nurse/Nurse Lecturer	No	
Dr Anthony White	Consultant Care of the Elderly	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Mrs Tracy Biggs	Research Ethics Committee Manager

Research and Development departments in NHS trusts (any minor amendments approved by the R&D sites were forwarded to both SOPREC and to NHS REC. Any documentation from NHS REC and SOPREC were also forward to the NHS R&D departments for their records.

WHYATT Kayley - Data Manager <Kayley.Whyatt@nottshc.nhs.uk>

RE: REC query: 160094 - 'Development and evaluation of a brief CFT intervention for trauma'.

To Claire Rycroft (13451708)

You forwarded this message on 02/06/2015 13:44.
We removed extra line breaks from this message.

Hi Claire,

Thank you for the confirmation.

Please accept this email as continuing NHS permission. You may now implement the changes.

Kind regards,

Kayley

Kayley Whyatt
Research and Development
Nottinghamshire Healthcare NHS Foundation Trust Duncan MacMillan House Porchester Road Mapperley
NG3 6AA

e: kayley.whyatt@nottshc.nhs.uk
t: 0115 9691300 ex: 11904

Follow us on Twitter @NottsHCRandD

For more information about conducting research within Nottinghamshire Healthcare NHS Foundation Trust, please visit our website: www.mentalhealthclinicians.org.uk

-----Original Message-----
From: Claire Rycroft (13451708) [mailto:13451708@students.lincoln.ac.uk]
Sent: 02 June 2015 13:38
To: WHYATT Kayley - Data Manager
Subject: RE: REC query: 160094 - 'Development and evaluation of a brief CFT intervention for trauma'.

Hi Kayley,

Yes I can confirm that the only document to be amended is:

Compassion Focused Therapy Five Minute Intervention Script (v.3, 13/05/2015)

This is following completion of my pilot phase and based on feedback from participants as per the original research protocol.

positive

Nottinghamshire Healthcare NHS
NHS Trust
Positive about integrated healthcare

research & development

Research and Development
Institute of Mental Health
University of Nottingham Innovation Park
Triumph Road
Nottingham
NG7 2TU

E-mail: shirley.mitchell@nottshc.nhs.uk
Direct Line: 0115 748 4321

Date of NHS Permission:13/01/2015

Miss Claire Rycroft
Lincolnshire Partnership Foundation Trust
College of Social Science
Brayford Pool
LN6 7TS

Dear Claire

Title: Development and evaluation of a brief CFT intervention in trauma
Chief Investigator: Claire Rycroft
Academic Supervisor: Thomas Schroder
Local Collaborator: Stephen Regal

Thank you for submitting your project to the Nottinghamshire Healthcare NHS Trust's R&D Department. The project has now been given NHS permission by:

Dr Julie Hankin: R & D Director, on behalf of Nottinghamshire Healthcare NHS Trust

NHS permission for the above research has been granted on the basis described in the application form, study protocol and supporting documentation.

Permission is granted on the understanding that the study is conducted in accordance with the Research Governance Framework, ICH GCP [ONLY if applicable], and NHS Trust policies and procedures available http://www.nottinghamshirehealthcare.nhs.uk/contact-us/freedom-of-information/policies-and-procedures/

The research sponsor or the Chief Investigator, or the local Principal Investigator at a research site, may take appropriate urgent safety measures in order to protect research participants against any immediate hazard to their health or safety. The R&D office should be notified that such measures have been taken. The notification should also include the reasons why the measures were taken and the plan for further action. The R&D Office should be notified within the same time frame of notifying the REC and any other regulatory bodies. All amendments (including changes to the local research team) need to be submitted in accordance with guidance in IRAS.

Please note that the NHS organisation is required to monitor research to ensure compliance with the Research Governance Framework and other legal and regulatory requirements. This is achieved by random audit of research.

Yours Sincerely

Shirley Mitchell
Head of Research Management and Governance

Lincolnshire Partnership NHS
NHS Foundation Trust

Date 29/12/14

Research Innovation &Effectiveness Team
Learning and Development Centre
Unit 3, The Reservation
East Road
SLEAFORD
Lincolnshire
NG34 7BY

Dear Emma Pearson

CONFIRMATION OF PRE-ENGAGEMENT CHECKS

Study name Developing and Evaluation of a brief CFT Intervention in trauma

Rec No 14/WA/1213

Researcher's name: Claire Rycroft

Job title: **Trainee Clinical Psychologist**

Contract end-date: 23/09/2016

Workplace and postal address: LPFT Community Forensic Team, Carholme Court, Long Leys Road Lincoln LN1 1FS

Academical Site: University of Lincoln

Electronic Staff Record number: - 24116851

DBS Enhanced Disclosure number 001408333706

Occupational Clearance has been given

As the representative of the NHS employer[1] of the above-named person, I can confirm that s/he is employed by this organisation. I understand that the responsibility for ensuring that the appropriate pre-engagement checks have been undertaken rests with us as the individual's substantive employer. I can confirm that the appropriate pre-engagement checks have been completed, commensurate with her/his job description and proposed research role in your NHS organisation, and in line with NHS employment checks standards.

Yours sincerely

Dianne Tetley

Dianne Tetley
Assistant Director of Research Innovation and Effectiveness

Lincolnshire Partnership NHS
NHS Foundation Trust

Our ref:
You ref: DT/TMc

Research, Innovation and Clinical Effectiveness
Learning and Development Centre
Unit 3, The Reservation
East Road
SLEAFORD
NG34 7BY

Tel: 01529 416255
Fax: 01529 222226
Email: research@lpft.nhs.uk

Date: 17 December 2014

Claire Rycroft
Trainee Clinical Psychologist
University of Lincoln
College of Social Science
Bridge House, Brayford Pool
LINCOLN
LN6 7TS

Dear Claire Rycroft

Study title: Development and evaluation of a brief CFT intervention in trauma
Chief Investigator: Claire Rycroft
REC No: 14/WA/1213
Date of permission: 17 December 2014

List of all site(s) for which NHS permission for research is given:

Lincolnshire Partnership NHS Foundation Trust

NHS permission for the above research has been granted by Lincolnshire Partnership NHS Foundation Trust on the basis described in the application form, protocol and supporting documentation.

Permission is granted on the understanding that the study is conducted in accordance with the Research Governance Framework, ICH GCP and NHS Trust policies and procedures (available at http://www.lpt.nhs.uk/).

Permission is only granted for the activities for which a favourable opinion has been given by the REC [and which have been authorised by the MHRA]

List of any conditions of approval: N/A

The research sponsor or the Chief Investigator, or the local Principal Investigator at a research site, may take appropriate urgent safety measures in order to protect research participants against any immediate hazard to their health or safety.

The Research and Effectiveness office should be notified, at the address above, that such measures have been taken. The notification should also include the reasons why the measures were taken and the plan for further action. The Research and Effectiveness Office should be notified within the same time frame of notifying the REC and any other regulatory bodies.

Any research carried out by a Trust employee with the knowledge and permission of the employing organisation will be subject to NHS indemnity. NHS indemnity provides indemnity against clinical risk arising from negligence through the Clinical Negligence Scheme for Trusts (CNST). Further details can be found at Research in the NHS: Indemnity arrangements (Department of Health 2005).

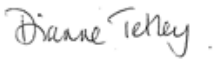
All amendments (including changes to the local research team) need to be submitted in accordance with guidance in IRAS.

Please inform the Research and Effectiveness department of any changes to study status.

Please note that the NHS organisation is required to monitor research to ensure compliance with the Research Governance Framework and other legal and regulatory requirements. This is achieved by random audit of research.

We are pleased to inform you that you may now commence your research. Please retain this letter to verify that you have Trust permission to proceed. We wish you every success with your work.

Yours sincerely



Dianne Tetley
Assistant Director Research, Innovation and Clinical Effectiveness
Lincolnshire Partnership NHS Foundation Trust

Cc Sponsor contact/supervisor - Thomas.schroder@nottingham.ac.uk
Local Collaborator – graham.evans@lpft.nhs.uk

Enc: Data Protection Guidance on the transportation of personal identifiable data

Appendix D: Recruitment Materials

Participant Information Sheet – Stage Two

PARTICIPANT INFORMATION SHEET

Title of Study: Evaluation of a brief Compassion Focused Therapy intervention before trauma-specific therapy.

Name of Researcher(s): **Claire Rycroft**

We would like to invite you to take part in our research study. This study is being undertaken as part of an educational project. Before deciding whether to participate, it is important that you understand why we are doing the study and what this will involve for you. Please read the following information carefully, and a researcher will contact you for an appointment if you wish to find out more and get involved. Feel free to talk to others about the study if you wish.

What is the purpose of the study?
We are carrying out a study involving people who are awaiting trauma-specific therapy. Our goal is to find out if brief self-practice compassion focused exercises are a helpful intervention before starting trauma-specific therapy.

We will want to look at whether people benefit from the self-practice and whether it helps the trauma-specific therapy that follows. This may provide information as to making the best use of time spent on a waiting list.

Service users have suggested that having additional support before starting trauma therapy can be useful and may lead to more benefits from the trauma therapy itself.

Why have I been invited?
This study will be available for those who are on the waiting list at the Centre for Trauma, Resilience and Growth and will involve around 40 individuals. Everyone will be given an equal chance to benefit from the intervention.

Do I have to take part?
You do not have to take part. It is completely up to you. If you choose not to take part in the study, this won't have a negative impact on your access to treatment at the trauma centre.

If you do decide to take part you will be given the opportunity to ask any questions before being asked to sign a consent form.

Taking part will not affect your time on the waiting list or access to treatment at the trauma centre, nor will it change the therapy offered to you by the trauma centre therapists.
You may withdraw from the study at any time and this will not affect your treatment at the trauma centre. If you wish to withdraw, any data after the first week of the intervention cannot be erased and may still be included in the

project analysis. However none of your personal details will be used and data will be anonymous.

What will happen to me if I take part?
If you choose to take part, the total time spent on the study will be up to 8 weeks. The trauma centre waiting list is currently up to for treatment is 8 weeks. The assessment waiting list, in line with trust policy is a maximum of 12 weeks.

Taking part in the study would involve:

> Attending an appointment with the researcher to take a measurement of your heart rate. This will be done with a heart rate monitor watch and chest strap, worn under your clothing. You will be given instructions about how to wear this and how it works.
>
> Completing questionnaires at the beginning, after three weeks of the intervention, before trauma-specific therapy, and after trauma-specific therapy. You will also be offered a follow up appointment after your trauma-specific therapy to see if any benefits have been maintained.
>
> Practicing five-minute exercises on a daily basis in your own time and completing a form telling us when you practiced. The exercises can be done at any time of the day and the monitoring sheet should be completed after your practice.

At the end of the study, we will compare the ratings on the questionnaires from before, during, and after the interventions to see if there have been any changes in these. We will also see if there are any changes in your resting heart rate by looking at the information from your appointments.

Your practice of the compassion-focused intervention may start straight away, or there may be a delay of up to four weeks. You will be randomly allocated to the immediate group or the delayed group. This will not affect your place on the waiting list at the trauma centre.

What are the possible disadvantages and risks of taking part?
There are no reported negative effects for practicing compassionate exercises. People can find compassionate imagery difficult. This might be in the form of difficult thoughts or emotions. However, research also suggests that continued practice can make this easier and people experience benefits from doing so.

What are the possible benefits of taking part?
Developing self-compassion is found to reduce self-criticism and feelings of shame and this may mean that you can benefit more from the trauma-specific therapy you are going to have. It may also reduce some of the symptoms associated with posttraumatic stress such as depression, and anxiety and stress.

We cannot promise the study will help you but the information we get from this study may help us to identify interventions which are helpful for trauma clients and offer improved care for those in similar circumstances as you.

What if there is a problem?
If at any time you find the intervention difficult or you need additional support, you will be encouraged to speak to the clinician who is assigned to you during your screening assessment at the trauma centre. They will be responsible for your care whilst on the waiting list.

If you have any other concerns about this study, please ask to speak to the researcher who will answer your questions as much as possible. Contact details are given at the end of this information sheet. You may contact the NHS Complaints department if you feel your concerns have not been address.

Will my taking part in the study be kept confidential?
Ethical and legal practice procedures will be followed and information about you will be held in confidence.

If you decide to take part, some parts of the data collected may be looked at by authorised persons from the University of Lincoln organising the research. They may be looked at to make sure the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and none of this information will include any of your personal details.

All information collected during the study will be anonymous, stored in a secure, locked office and on a password-protected database. Any of your data which leaves the trauma centre will have your personal details removed and a unique code will be used so that you cannot be recognised from it.

All research data will be kept securely for 7 years. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality. No person identifiable information will be held.

Your GP will be informed of your participation in the study, although they will not be provided with your data or results from the study.

What will happen to the results of the research study?
The results of the study will be written up in a report, which may be published in a journal paper (you will be informed if this is the case). If you wish to request a copy of the final report you may do so. The write up is estimated to be completed in November 2015 and a finalised report available by March 2016.

Who is organising and funding the research?
The study is overseen by the University of Lincoln.

Who has reviewed the study?
All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by Wales REC 4 review board and by the Research and Development board of Nottinghamshire Healthcare NHS.
Further information and contact details

If you have any queries or would like further information about the research, please contact Claire Rycroft on Claire.Rycroft@nhs.net or 07519 343062.

Should you wish to raise any complaints, you may contact the School of Psychology Research Ethics Committee, College of Social Science, University of Lincoln, Brayford Pool, Lincoln, Lincolnshire. LN6 7TS. Email: Soprec@lincoln.ac.uk.

UNIVERSITY OF LINCOLN

CONSENT FORM

Title of Project: Evaluation of a brief Compassion Focused Therapy intervention before trauma-specific therapy.

Name of Researcher: **Claire Rycroft**

Please initial all boxes

1. I confirm that I have read and understand the information sheet dated **……..** for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my care or legal rights being affected. I also acknowledge that any data collected after the first week of the intervention cannot be erased and may still be used in the project analysis. ☐

3. I understand that my data collected during the study will be used anonymously and be included in the final write up of **Claire Rycroft's** study. I give permission for my data to be used in this way. ☐

4. I understand that my therapist at the Centre for Trauma, Resilience and Growth may be asked to complete a questionnaire about the trauma-focused therapy sessions. This will not use any identifiable data about me and will focus solely on the therapist's practice. ☐

5. I understand that my GP will be informed that I am participating in this study and I give permission for this. ☐

6. I agree to take part in the above study. ☐

_____	_____	_____
Name of Participant	Date	Signature
_____	_____	_____
Name of Person taking consent.	Date	Signature

UNIVERSITY OF LINCOLN

GP LETTER

Dear Dr.

I am writing to inform you that the above patient has agreed to take part in a research study which is being conducted as part of a Doctoral Programme in Clinical Psychology. The patient has given their consent for you to be informed of their involvement. Please find enclosed a copy of the participant information sheet to inform you of the details of the study.

It has been agreed that the patient's personal study data and results will not be shared and these will be included anonymously only in the final research report.

Yours sincerely

Claire Rycroft

Trainee Clinical Psychologist

Appendix E: CFT intervention script following adaptation for phase one.

Compassion Focused Therapy Five Minute Intervention Script

5 minute Compassion Practice

Welcome to this work seeing how a regular focus on oneself as a compassionate person can be helpful to us in our everyday life. How does it work? We don't often think about trying to become a certain kind of person. We might practice playing the piano or football skills but not becoming a certain kind of person. If you think about it, you will notice that most of the time we just feel and act certain ways because of the things that are happening around us. So, for example, if someone annoys us we feel anger and may respond with anger, or if someone makes us anxious we might then respond with being anxious and perhaps submissive. But suppose neither of those responses are really what you want. How could we think about and begin to practice being in the world as a person who we really want to be?

The essence of compassion self-practice is to focus and imagine the kind of compassionate self we would like to be. Why choose a compassionate self? The reason to focus on compassion is because compassion helps us act in ways that are helpful for our well-being and that of others. Compassion is also a source of enormous courage. For example, imagine you have to go to the hospital for some worrying tests, or you're going through a difficult situation in life, like a divorce. What would you want from your most compassionate friend? Well you would certainly want understanding, kindness and support to help you settle a bit. But you would also want your friend to help you face what you need to face - to give you courage. It wouldn't be very useful if your friend said 'It's all too frightening, why not to stay at home?'

So compassion is an ability to pay attention to the suffering and difficulties in yourself and others and try to build the courage and wisdom to do what we can to be helpful.

Building your compassionate self

First think about all the qualities you would have if you are at your compassionate best. For example, if a friend was struggling with something, how would you really like to be with them? Or imagine an argument with someone you like. If you are at your calmest compassionate best - how would you deal with this? Make a note of those qualities you see yourself enacting.

They could include patience, strength, friendliness, confidence and wisdom. Basically in a moment, we are going to simply practice imagining having those key qualities and how we would act when we were in a compassionate state of mind.

Take a few moments to make yourself a list, and then work through the following exercises, pausing where you need to and give yourself time. Once you have worked through them a few times, you might find them easier to do, and need less time to pause in between exercises.

Here are the exercises

1. Soothing rhythm breathing - 45 seconds
We can help to create a compassionate sense of self by paying attention to our body and in particular our breathing. If we slightly deepen and slow the breath we might notice a sense of slowing down inside. This might come with a feeling of the body becoming slightly heavier. If we speed up our breathing, we are more likely to feel a bit lightheaded.

Sitting or standing comfortably, allow air to go in through your nose and down into your diaphragm. Then after a short pause let it come out naturally, again through your nose. Try not to force it out but just allow it to come out naturally and easily. So nice smooth breaths in and out – this might take a bit of practice.

Now, breathe slightly slower and deeper than you would normally. This is called soothing rhythm breathing. While you can find a pace for breathing that you're comfortable with, you can try counting from 1 to 4 or 5 (a second at a time). Do this for the in-breath, hold for a short pause and then allow the breath to come out again through the nose on a count of about 1 to 4-5. Find what feels comfortable for you.

Once you have the hang of it, you don't need to count unless it helps you, but you are aiming for about 5-6 breaths per minute. So try this for about 45 seconds. The key thing to notice is the sense of slowing down inside and your body becoming a little heavier. It can sometimes help to place your right hand on your heart and think about feeling the breaths smoothly and deeply into this area.

2. Say 'Hello' to yourself – 15 seconds neutral, 15 seconds friendly
Next keep doing this soothing breathing but now focus on creating a friendly facial expression and a friendly voice tone too. On the out breath, say hello to yourself. Say "hello" followed by your first name. First, try a neutral way and second, try a friendly way – as if you are talking to someone you care about. So focus first on the out-breath with a neutral facial expression and voice tone - say hello to yourself for the next 15 seconds. Then have 15 seconds of creating a gentle, friendly facial expression and friendly voice to say hello to yourself.

Take a moment to see what you can notice. Sometimes we notice that creating a friendly voice tone offers a slight change of feeling. Having friendly textures to our thoughts stimulates systems in our brain that are helpful for well-being. If we create hostile textures to thoughts or become self-judgemental, this is not helpful to our well-being and can contribute to feeling anxious or depressed.

Each time you find yourself hearing self-critical thoughts or judgments, take a few deep breaths and try and refocus on friendly thoughts and saying hello to yourself in a friendly way.

3. Imagine having ideal compassionate qualities – 45 seconds
The next exercise is to continue the soothing breathing, friendly facial expressions and voice tones, whilst imagining yourself at your compassionate best. So keep your soothing rhythm breathing and begin to imagine yourself

having your ideal compassionate qualities. These could be patience, confidence, courage, wisdom, caring, strength or others. Try to recognise three particular qualities that are meaningful to you. Spend 45 seconds with a friendly facial expression and imagine being in the world with these qualities – How are you acting? How do others react to you? Make a commitment to try to be helpful when things are difficult either for you or for others.

4. Focusing compassion on others – 1 minute
Now this really gets going when we focus on it. So for the next minute, bring someone to mind who you care about and on the out breath focus on the wish for them to find peace and be happy. You can say in your mind 'May you find peace', 'May you be happy' and name that person. As you do this, try to create that friendly voice tone and facial expression. Do that for one minute and see what happens.

Notice how that made you feel. Now we are going to focus your compassionate self on you. Sometimes people find this more difficult, so don't worry about it, just see how far you get.

5. Focusing compassion on self – 1 minute
So keeping your soothing rhythm breathing and your compassionate voice tone and facial expression, imagine you can see yourself in your mind's eye and focus on the idea of: 'May you find peace; may you be happy'. Sometimes people like to think of it as may 'I' find peace, may I be happy. Others like to focus on naming themselves. Remember to also focus on the pleasure you would get if this could be true. Try this for one minute.

Some people commonly note some resistance to this, as if they're not entitled to compassion – which is sad really because compassion is a way of building strengths. But if that's true for you don't worry. Just focus on the idea 'May I be compassionate to that which resists compassion.

Each time you find yourself hearing self-critical thoughts or judgments, take a few deep breaths and try and refocus on friendly thoughts. Repeat the words 'May you find peace; may you be happy' in your best compassionate way.

6. Focusing compassion on challenges – 1 minute
Next think of a situation that is slightly difficult for you -- nothing too hard to begin with. Please do not focus on traumatic events you may have experienced. Choose a mild difficulty or minor stressful situation for this exercise.

Move into the compassionate self with all those qualities that you have imagined and a real intent to become a confident, compassionate person who brings wisdom, strength and commitment to situations. Imagine how you, as this most compassionate person, want to deal with this challenging situation. See if any new insights or ideas come to mind. Sometimes it can be helpful to write about situations that are bothering us but through the eyes of a compassionate other. Spend one minute focusing on this.

Keep going

Continue to try putting yourself into a compassionate space where you practice slowing your breath, creating a compassionate voice tone and allowing yourself to feel what it might be like to be this most compassionate person. Even after you have finished practice just allow yourself to continue walking around and holding on to that sense of being a compassionate self.

Each time you find yourself hearing self-critical thoughts or judgments, take a few deep breaths and try and refocus on friendly thoughts. Repeat the words 'May you find peace; may you be happy' in your best compassionate way.

As you practice you may notice that perhaps you want to do more compassionate things, even small things like take more of an interest in others or say hello in a more friendly way. Notice if you are someone who tends to be critical of yourself or gets easily disappointed and frustrated. These emotions are very easy to stimulate within us but are not helpful. Try to notice when they arise and switch to a 'compassionate voice'. This is not letting yourself off the hook in anyway because compassion will always face the issues - it is just doing it in a way that is helpful. So one trick is to always notice how you talk to yourself and use your ability to create a friendly voice in your head. Try not to speak to yourself in a tone or way that you wouldn't want to use to talk to a friend.

Your five-minute practice

1. Soothing rhythm breathing - 45 seconds

2. Say 'Hello' to yourself – 15 seconds neutral, 15 seconds friendly

3. Imagine having ideal compassionate qualities – 45 seconds

4. Focusing compassion on others – 1 minute

5. Focusing compassion on self – 1 minute

6. Focusing compassion on little challenges – 1 minute

If you wish to spend longer on this practice, please do so. It may be helpful to spend extra time on practicing compassion for yourself and small challenges you may be facing. It is important that you do not use these exercises to focus on traumatic events, as these will be explored with support from your therapist once you begin formal therapy.

Appendix F: Participant Monitoring Sheet, phases one and two.

Participant monitoring sheet for interventions

DAILY MONITORING

Patient Identification Number:

Date	Time (when)	Time spent	Comments (optional)

Appendix G: Phase one feedback from

Feedback Form - Stage One

FEEDBACK QUESTIONNAIRE

1. How easy did you find the instructions to follow when practicing the exercises?

Very Easy	Easy	Average	Difficult	Extremely difficult
0	**1**	**2**	**3**	**4**

2. How useful did you find practicing the exercises?

Not useful	A little	Somewhat	Useful	Very Useful
0	**1**	**2**	**3**	**4**

3. How much did you use the practices over the two week period?

Never	Once or twice	Occasionally	Every other day	Daily
0	**1**	**2**	**3**	**4**

4. Do you think you will continue to use this? (Please circle)

Yes **No**

Do you have any other comments about your experience? (What was good or bad about it? What would you change?)

_____

_____

_____

Appendix H: Phase One qualitative transcripts.

P1 - Found it difficult to do but has made me want to explore it further. I feel it's making me move forwards into unfamiliar but positive territory. It's had a positive impact on my relationship with my girlfriend. The CD is most helpful, but it would be better to have the pauses built in so that it doesn't break your focus. That was a bit disruptive at times. It'd be like being gifted the time to give it a go. The intro is good as it's getting you into the mind set straight away. Good tempo and good voice. There were very human elements rather than it being too clinical. The ideas do become less frightening once you're more familiar

P2 - Really well thought out and structured. Good that it fitted into five minutes and soon became a pleasure to do and looked forward to it. Began using all materials and as I practiced more I just used the prompts on the final page of the written version. Found it best sitting alone without distractions and least effective when lying down as I dozed off. I found it applicable to expanding to different situations. Practice was uplifting. Exercise 2 was surprisingly the most profound in providing a lovely feeling. Feel it's unearthed a resource in myself to be able to be kind to myself and I feel more confident and assertive. Would recommend it to anyone.

P3 - Being in front of a mirror for exercise 2 helped. Felt a little ridiculous but it got better. It's not yet automatic but I hope to continue practice and improve. Knowing I have something else is helpful. It is helpful to suggest to people to have a regular time each day to practice - this helped me. I'm more aware of how I speak to people now and things feel smoother.

P4 - Looking in the mirror made it difficult. I was more able to be compassionate to others. Would like to practice this again. Maybe it would be good to have a choice to use a mirror or not?

P5 - It was an interesting format and nice to have the choice of reading or listening - I found the CD easier to use. I wouldn't suggest anything to change it, it's good. Except to leave gaps in between the exercises on CD. I would have found this really helpful in the past at a time when I was struggling more and I can see that it would be good to use when your therapist isn't around.

P6 - The part in the intro about textures and feelings was really good and I could relate to this. It's good to have a general introduction like this first. It's one of those things where it might work, but even if it doesn't you've practiced spending some time thinking about positive things. It feels like I was learning a skill but it's hard to see what it was or how it worked but when in a difficult situation you could expect it to have an impact. Recently went in A&E and

would normally react angrily at treatment from Drs and nurses and found that although not consciously thinking of the CFT exercises, I didn't react angrily and the situation was very different. I can't think of anything else that is any different to attribute it to.

P7 - I would practice some bits in the future more than others. The breathing exercise was particularly helpful. I do feel much calmer and less anxious and I haven't changed anything else that I could put this down to. I found it helpful to visualise when saying hello to myself. Maybe more visual instructions would help. It's easy to fit into the day.

P8 - I found some of the exercises hard initially as it's new to me. If I was having a bad day I really wanted to give up but when I came back to it, it really helped. I will keep using it as it's getting a bit easier to practice. I don't have to go through all the instructions as much now. Having a set time is helpful so maybe suggest this to people.

Appendix I: CFT intervention with tracked changes.

Compassion Focused Therapy Five Minute Intervention Script

5 minute Compassion Practice

Welcome to this work seeing how a regular focus on oneself as a compassionate person can be helpful to us in our everyday life. How does it work? We don't often think about trying to become a certain kind of person. We might practice playing the piano or football skills but not becoming a certain kind of person. If you think about it, you will notice that most of the time we just feel and act certain ways because of the things that are happening around us. So, for example, if someone annoys us we feel anger and may respond with anger, or if someone makes us anxious we might then respond with being anxious and perhaps submissive. But suppose neither of those responses are really what you want. How could we think about and begin to practice being in the world as a person who we really want to be?

The essence of compassion self-practice is to focus on and imagine the kind of compassionate self we would like to be. Why choose a compassionate self? The reason to focus on compassion is because compassion helps us act in ways that are helpful for our well-being and that of others. Compassion is also a source of enormous courage. For example, imagine you have to go to the hospital for some worrying tests, or you're going through a difficult situation in life, like a divorce. What would you want from your most compassionate friend? Well you would certainly want understanding, kindness and support to help you settle a bit. But you would also want your friend to help you face what you need to face - to give you courage. It wouldn't be very useful if your friend said 'It's all too frightening, just stay at home?'

So compassion is an ability to pay attention to the suffering and difficulties in yourself and others and try to build the courage and wisdom to do what we can to be helpful.

Building your compassionate self

First think about all the qualities you would have if you are at your compassionate best. For example, if a friend was struggling with something, how would you really like to be with them? Or imagine an argument with someone you like. If you are at your calmest compassionate best - how would you deal with this? Make a note of those qualities you see yourself enacting.

They could include patience, strength, friendliness, confidence and wisdom. Basically in a moment, we are going to simply practice imagining having those key qualities and how we would act when we were in a compassionate state of mind.

Take a few moments to make yourself a list, and then work through the following exercises, pausing where you need to and give yourself time. Once you have worked through them a few times, you might find them easier to do, and need less time to pause in between exercises.

Here are the exercises

1. Soothing rhythm breathing - 45 seconds
We can help to create a compassionate sense of self by paying attention to our body and in particular our breathing. If we slightly deepen and slow the breath we might notice a sense of slowing down inside. This might come with a feeling of the body becoming slightly heavier. If we speed up our breathing, we are more likely to feel a bit lightheaded.

Sitting or standing comfortably, allow air to go in through your nose and down into your diaphragm. Then after a short pause let it come out naturally, again through your nose. Try not to force it out but just allow it to come out naturally and easily. So nice smooth breaths in and out – this might take a bit of practice.

Now, breathe slightly slower and deeper than you would normally. This is called soothing rhythm breathing. While you can find a pace for breathing that you're comfortable with, you can try counting from 1 to 4 or 5 (a second at a time). Do this for the in-breath, hold for a short pause and then allow the breath to come out again through the nose on a count of about 1 to 4 or 5. Find what feels comfortable for you.

Once you have the hang of it, you don't need to count unless it helps you, but you are aiming for about 5-6 breaths per minute. So try this for about 45 seconds. The key thing to notice is the sense of slowing down inside and your body becoming a little heavier. It can sometimes help to place your right hand on your heart and think about feeling the breaths smoothly and deeply into this area.

2. Say 'Hello' to yourself – 15 seconds neutral, 15 seconds friendly
Next keep doing this soothing breathing but now focus on creating a friendly facial expression and a friendly voice tone too. You may find it helpful to see yourself in front of a mirror, if you are comfortable with this. Instead, you may wish to focus on the sensations of your facial expression and voice tone. Either is fine.

On the out breath, say hello to yourself. Say "hello" followed by your first name. First, try a neutral way. Focus first on the out-breath with a neutral facial expression and voice tone - say hello to yourself for the next 15 seconds.

And now try a friendly way – as if you are talking to someone you care about. Then have 15 seconds of creating a gentle, friendly facial expression and friendly voice to say hello to yourself.

Take a moment to see what you can notice. Sometimes we notice that creating a friendly voice tone offers a slight change of feeling. Having friendly textures to our thoughts stimulates systems in our brain that are helpful for well-being. If we create hostile textures to thoughts or become self-judgemental, this is not helpful to our well-being and can contribute to feeling anxious or depressed.

Each time you find yourself hearing self-critical thoughts or judgments, take a few deep breaths and try and refocus on friendly thoughts and saying hello to yourself in a friendly way.

3. Imagine having ideal compassionate qualities – 45 seconds
The next exercise is to continue the soothing breathing and friendly facial expressions and voice tones, whilst imagining yourself at your compassionate best. So keep your soothing rhythm breathing and begin to imagine yourself having your ideal compassionate qualities. You may wish to use your list that you created at the beginning. These qualities could be patience, confidence, courage, wisdom, caring, strength or others. Try to recognise and focus on three particular qualities that are meaningful to you. Spend 45 seconds with a friendly facial expression and imagine being in the world with these qualities – How are you acting? How do others react to you? Make a commitment to try to be helpful when things are difficult either for you or for others.

4. Focusing compassion on others – 1 minute
Now this really gets going when we focus on it. So for the next minute, bring someone to mind who you care about and on the out breath focus on the wish for them to find peace and be happy. You can say in your mind 'May you find peace', 'May you be happy' and name that person. As you do this, try to create that friendly voice tone and facial expression. Do that for one minute and see what happens.

Notice how that made you feel.

Now we are going to focus your compassionate self on you. Sometimes people find this more difficult, so don't worry if you do, just see how far you get.

5. Focusing compassion on self – 1 minute
Keeping your soothing rhythm breathing and your compassionate voice tone and facial expression, imagine you can see yourself in your mind's eye and focus on the idea of: 'May you find peace; may you be happy'. Sometimes people like to think of it as may 'I' find peace, may I be happy. Do whichever makes you feel most comfortable. Others like to focus on naming themselves. Remember to also focus on the pleasure you would get if this could be true.

Some people commonly note some resistance to this, as if they're not entitled to compassion – which is sad really because compassion is a way of building strengths. But if that's true for you don't worry. Just focus on the idea 'May I be compassionate to that which resists compassion.

Each time you find yourself hearing self-critical thoughts or judgments, take a few deep breaths and try and refocus on friendly thoughts. Repeat the words 'May you find peace; may you be happy' in your best compassionate way.

So for the next one minute, spend some time keeping yourself in your mind's eye, focusing on the idea may I find peace, may I be happy.

6. Focusing compassion on challenges – 1 minute
Next think of a situation that is slightly difficult for you -- nothing too hard to begin with. Please do not focus on traumatic events you may have experienced. Choose a mild difficulty or minor stressful situation for this exercise. Spend a few moments thinking of a situation you can focus on.

Move into the compassionate self with all those qualities that you have imagined and a real intent to become a confident, compassionate person who brings wisdom, strength and commitment to situations. Imagine how you, as this most compassionate person, want to deal with this challenging situation. See if any new insights or ideas come to mind. Spend one minute focusing compassion on this difficulty.

Sometimes it can be helpful to write about situations that are bothering us but through the eyes of a compassionate other. This may be something you want to do separately.

Keep going
Continue to try putting yourself into a compassionate space where you practice slowing your breath, creating a compassionate voice tone and allowing yourself to feel what it might be like to be this most compassionate person. Even after you have finished practice just allow yourself to continue walking around and holding on to that sense of being a compassionate self.

Each time you find yourself hearing self-critical thoughts or judgments, take a few deep breaths and try and refocus on friendly thoughts. Repeat the words 'May I find peace; may I be happy' in your best compassionate way.

As you practice you may notice that perhaps you want to do more compassionate things, even small things like take more of an interest in others or say hello in a more friendly way. Notice if you are someone who tends to be critical of yourself or gets easily disappointed and frustrated. These emotions are very easy to stimulate within us but are not helpful. Try to notice when they arise and switch to a 'compassionate voice'. This is not letting yourself off the hook in anyway because compassion will always face the issues - it is just doing it in a way that is helpful. So one trick is to always notice how you talk to yourself and use your ability to create a friendly voice in your head. Try not to speak to yourself in a tone or way that you wouldn't want to use to talk to a friend.

Your five-minute practice
1. Soothing rhythm breathing - 45 seconds
2. Say 'Hello' to yourself – 15 seconds neutral, 15 seconds friendly
3. Imagine having ideal compassionate qualities – 45 seconds
4. Focusing compassion on others – 1 minute
5. Focusing compassion on self – 1 minute
6. Focusing compassion on little challenges – 1 minute

If you wish to spend longer on this practice, please do so. It may be helpful to spend extra time on practicing compassion for yourself and small challenges you may be facing. It is important that you do not use these exercises to focus on traumatic events, as these will be explored with support from your therapist once you begin formal therapy

Appendix J: Phase Two Participant feedback form.

FEEDBACK QUESTIONNAIRE

1. How easy did you find the instructions to follow when practicing the exercises?

Very Easy Easy Average Difficult Extremely difficult

0 1 2 3 4

2. How useful did you find practicing the exercises?

Not useful A little Somewhat Useful Very Useful

0 1 2 3 4

3. How much did you use the practices over the three week period?

Never Once or twice Occasionally Every other day Daily

0 1 2 3 4

4. Do you think you will continue to use this? (Please circle)

Yes No

5. Did you continue to use this (if in the immediate group)? (Please circle)

Yes No

Do you have any other comments about your experience?

Appendix K – raw data used for RCI calculations

Dass-21 – Total score. Taken from Cooper (2011) for the clinical norms and Henry and Crawford (2005) for general population norms.

Sample	N	Mean	SD
Community	1794	9.43	9.66
Trauma population	60	40.72	16.96

FSCRS – IS. Taken from Baiao, Gilbert, McEwan & Carvalho (2014)

Sample	N	Mean	SD
Clinical	167	27.47	7.51
Non-clinical	887	17.72	8.29

FSCRS – HS. Taken from Baiao, Gilbert, McEwan & Carvalho (2014)

Sample	N	Mean	SD
Clinical	167	12.26	5.67
On-clinical	887	3.88	4.59

FOC. Taken from Gilbert, et. al. (2010).

Sample	N	Mean	SD
Clinical			
Non-clinical	222	16.12	10.38

Evaluation of a brief self-practice CFT intervention: Phase Two

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1. Introduction

Exposure to traumatic events is common[1]. For those who do not then develop PTSD, some will experience debilitating traumatic stress symptoms which may be considered 'subclinical' [2,3]. Current evidence-based guidelines focus on treating clinical PTSD[4]. However, a more dimensional approach to traumatic stress may be beneficial to a larger group of people[5]. Traumatic stress frequently results in associated symptoms of depression and anxiety and other psychological difficulties[6]. Other factors have been found to be important in considering the maintenance of trauma symptoms, and thus warrant further exploration. These include self-criticism[7], self-compassion[8], and Heart Rate Variability[9] (HRV).

Interventions focused on strategies to reduce self-criticism and increase self-compassion may provide an important adjunct to facilitate traditional trauma therapies[5] by reducing symptoms of depression, anxiety, and stress in order facilitate improved outcomes in subsequent therapies. A self-practice CFT intervention was evaluated in a pilot-RCT with a trauma population. Although significant group effects were not found, symptoms of depression, anxiety, and stress, and trauma symptoms did reduce.

2. Aims

- To establish effectiveness of a modified brief CFT intervention in a pilot-RCT for a trauma population
- To evaluate the intervention regarding its effects on factors associated with the maintenance of trauma symptoms

4. Design

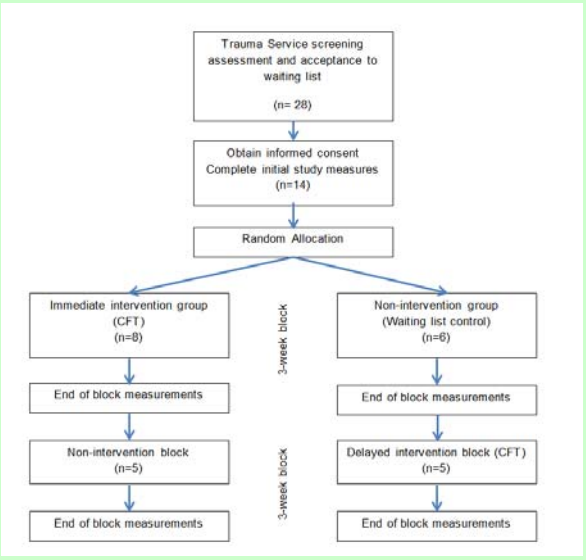
Participants from a specialist trauma service were randomised to one of two conditions (see study procedure.

At each measurement point they completed the following assessments:

Depression, Anxiety & Stress Scale (DASS-21); Impact of Events Scale-Revised (IES-R); Self-Compassion Scale (SCS); Fear of Compassion scale (FOC); Forms of Self-Criticising/Attacking & Self-Reassuring Scale (FSCRS); Psychological Well-being – Post-Traumatic Change Questionnaire (PWB-PTCQ); Social Safeness and Pleasure Scale (SSPS) . Measurement of HRV was also taken.

For three of the six weeks participants were involved they were required to practice five-minute CFT exercises on a daily basis.

3. Study Procedure



5. Findings

- 10 participants completed the pilot-RCT (6 men, 4 women). Mean age was 47.10 years (*SD* = 12.57) and had experienced a range of traumatic events.
- Repeated measures ANOVAs did not demonstrate significant interaction effects for time and group across the measures. However;
- Significant main effects of time were found for depression $F(2, 16) = 4.729$, $p = .024$, partial $\eta^2 = .372$, total IES-R scores $F(2, 16) = 17.147$, $p < .00$, partial $\eta^2 = .682$ and subscales of self-criticism $F(2, 16) = 7.845$, $p = .004$, partial $\eta^2 = .495$, $F(2, 16) = 7.246$, $p = .020$, partial $\eta^2 = .475$

6. Discussion & Implications

- The study was underpowered and therefore statistical analysis is tentative at this stage.
- Changes on the assessment measures were in the hypothesised directions.
- Recruitment continues in order to support the power of the study.
- The trial offers a starting point to develop intervention research regarding CFT and self-practice.

[1]Bonanno, G. A. (2008). Loss, trauma, and human resilience: Have we underestimated the human capacity to thrive after extremely aversive events? *Psychological Trauma: Theory, Research, Practice, and Policy, S*(1), 101-113. doi:10.1037/1942-9681.S.1.101. [2]Dickstein, B. D., Walter, K. H., Schumm, J. A., & Chard, K. M. (2013). Comparing response to cognitive processing therapy in military veterans with subthreshold and threshold posttraumatic stress disorder. *Journal of Traumatic Stress, 26*(6), 703-709. doi:10.1002/jts.21869. [3]Mitchell, K. S., Mazzeo, S. E., Schlesinger, M. R., Brewerton, T. D., & Smith, B. N. (2012). Comorbidity of partial and subthreshold PTSD among men and women with eating disorders in the national comorbidity survey-replication study. *International Journal of Eating Disorders, 45*(3), 307-315. doi:10.1002/eat.20965. [4]National Institute of Clinical Excellence. (2005). *Post-Traumatic Stress Disorder: The Management of PTSD in Adults and Children in Primary and Secondary Care.* [5]Harman, R., & Lee, D. (2010). The role of shame and self-critical thinking in the development and maintenance of current threat in post-traumatic stress disorder. *Clinical Psychology & Psychotherapy, 17*(1), 13-24. [6]McEwan, K. & Gilbert, P. (2013). *The effects of two weeks practising three compassionate focused therapy exercises in a nonclinical population*. Manuscript submitted for publication. [7]Whelton, W. J., & Greenberg, L. S. (2005). Emotion in self-criticism. *Personality and Individual Differences, 38*(7), 1583-1595. [8]Cooper, A. M. (2011). *Does self-compassion act as a moderator for risk factors associated with PTSD symptom severity?* University of Nottingham. [9]Chang, H., Chang, C., Tzeng, N., Kuo, T. B., Lu, R., & Huang, S. (2013). Decreased cardiac vagal control in drug-naïve patients with posttraumatic stress disorder. *Psychiatry Investigation, 10*(2), 121-130.